Schedule of Pharmaceutical Benefits

Effective 1 November 2017

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

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Fees, Patient Contributions and Safety Net Thresholds

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

<table>
<thead>
<tr>
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<tr>
<td>Extemporaneously-prepared</td>
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<tr>
<td>Allowable additional patient charge*</td>
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<td><strong>Additional Fees (for safety net prices):</strong></td>
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* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.
Summary of Changes

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

**General Pharmaceutical Benefits**

**Additions**

**Addition – Item**

- **11191B** CEFUROXIME, cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL *(Zinnat)* (Dental)
- **11192C** CEFUROXIME, cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL *(Zinnat)*
- **11193D** EVOLOCUMAB, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

**Addition – Brand**

- **1007B** Aciclovir AN, ED – ACICLOVIR, aciclovir 200 mg tablet, 90
- **1891M** AMCLAVOX DUO 500/125, RW – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10
- **5008N** AMCLAVOX DUO 500/125, RW – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10
- **5006L** AMCLAVOX DUO FORTE 875/125, RW – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10
- **8254K** AMCLAVOX DUO FORTE 875/125, RW – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10
- **2729P** APO-Baclofen, TX – BACLOFEN, baclofen 10 mg tablet, 100
- **2730Q** APO-Baclofen, TX – BACLOFEN, baclofen 25 mg tablet, 100
- **8600P** Pharmacor Esomeprazole, CR – ESOMEPRAZOLE, esomeprazole 20 mg enteric tablet, 30
- **8886Q** Pharmacor Esomeprazole, CR – ESOMEPRAZOLE, esomeprazole 20 mg enteric tablet, 30
- **3401B** Pharmacor Esomeprazole, CR – ESOMEPRAZOLE, esomeprazole 40 mg enteric tablet, 30
- **8601Q** Pharmacor Esomeprazole, CR – ESOMEPRAZOLE, esomeprazole 40 mg enteric tablet, 30
- **1835N** GAPENTIN, RF – GABAPENTIN, gabapentin 400 mg capsule, 100
- **2348N** Blooms The Chemist Pregabalin, IB – PREGABALIN, pregabalin 25 mg capsule, 56
- **2348N** Neuroccord, CR – PREGABALIN, pregabalin 25 mg capsule, 56
- **2348N** Pregabalin AMNEAL, EA – PREGABALIN, pregabalin 25 mg capsule, 56
- **2335X** Blooms The Chemist Pregabalin, IB – PREGABALIN, pregabalin 75 mg capsule, 56
- **2335X** Neuroccord, CR – PREGABALIN, pregabalin 75 mg capsule, 56
- **2335X** Pregabalin AMNEAL, EA – PREGABALIN, pregabalin 75 mg capsule, 56
- **2355Y** Blooms The Chemist Pregabalin, IB – PREGABALIN, pregabalin 150 mg capsule, 56
- **2355Y** Neuroccord, CR – PREGABALIN, pregabalin 150 mg capsule, 56
- **2355Y** Pregabalin AMNEAL, EA – PREGABALIN, pregabalin 150 mg capsule, 56
- **2363J** Blooms The Chemist Pregabalin, IB – PREGABALIN, pregabalin 300 mg capsule, 56
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<td>Pregabalin AMNEAL, EA – <strong>PREGABALIN</strong>, pregabalin 300 mg capsule, 56</td>
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<td>Sandoz Venlafaxine XR, HX – <strong>VENLAFAXINE</strong>, venlafaxine 75 mg modified release capsule, 28</td>
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<td>Sandoz Venlafaxine XR, HX – <strong>VENLAFAXINE</strong>, venlafaxine 150 mg modified release capsule, 28</td>
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**Deletions**

### Deletion – Brand

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<td>Atorvastatin AN, EA – <strong>ATORVASTATIN</strong>, atorvastatin 80 mg tablet, 30</td>
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<td>Azamun, ED – <strong>AZATHIOPRINE</strong>, azathioprine 50 mg tablet, 100</td>
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<td>Biso 5, ED – <strong>BISOPROLOL</strong>, bisoprolol fumarate 5 mg tablet, 28</td>
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<td>Biso 10, ED – <strong>BISOPROLOL</strong>, bisoprolol fumarate 10 mg tablet, 28</td>
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**Deletion – Equivalence Indicator**

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**Deletion – Note**

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<td>ETANERCEPT, etanercept 25 mg injection [4 vials] (&amp;) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)</td>
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<tr>
<td>9429G</td>
<td>ETANERCEPT, etanercept 25 mg injection [4 vials] (&amp;) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Alterations

Alteration – Brand Name

From
8804J Lophlex, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 27.8 g sachets

To
8804J PKU Lophlex, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 27.8 g sachets

Alteration – Restriction

9186L ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes (Humira)
9187M ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (Humira)
9188N ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira)
9190Q ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (Humira)
1954W ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)
8637N ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)
8638P ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)
9037P ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)
9429G ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)

Alteration – Manufacturer Code

8256M Dilatrend 6.25 – CARVEDILOL, carvedilol 6.25 mg tablet, 60
8257N Dilatrend 12.5 – CARVEDILOL, carvedilol 12.5 mg tablet, 60
8258P Dilatrend 25 – CARVEDILOL, carvedilol 25 mg tablet, 60

Alteration – Maximum Quantity

From
8804J AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 27.8 g sachets (PKU Lophlex)
9021T AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans (PKU Lophlex LQ 20)

Advance Notices

1 December 2017
Deletion – Brand

10932J Ridaura, GH – AURANOFIN, auranofin 3 mg tablet, 100
8883M Avanza, MK – MIRTAZAPINE, mirtazapine 45 mg tablet, 30

1 January 2018
Deletion – Brand

1411G add-ins, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1
1892N Augmentin, AS – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
5009P Augmentin, AS – AMOXYCILLIN + CLAVULANIC ACID, amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
10778G Ialex, LN – CEPHALEXIN, cephalaxin 500 mg capsule, 20
2655R Ialex, LN – CEPHALEXIN, cephalaxin 250 mg capsule, 20
3058Y Ialex, LN – CEPHALEXIN, cephalaxin 250 mg capsule, 20
3094W Ialex, LN – CEPHALEXIN, cephalaxin 125 mg/5 mL powder for oral liquid, 100 mL
Palliative Care
Alterations
Alteration – Maximum Quantity

<table>
<thead>
<tr>
<th>Item</th>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>FENTANYL</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Highly Specialised Drugs Program (Private Hospital)
Additions
Addition – Item
11194E BACLOFEN, baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule (Sintetica Baclofen Intrathecal)

Addition – Note
10398G VEDOLIZUMAB, vedolizumab 300 mg injection, 1 vial (Entyvio)

Deletions
Deletion – Note
10184B INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
9612X INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
9613Y INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)

Alterations
Alteration – Note
10184B INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)

 Alteration – Restriction
9613Y INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
10398G VEDOLIZUMAB, vedolizumab 300 mg injection, 1 vial (Entyvio)
10415E VEDOLIZUMAB, vedolizumab 300 mg injection, 1 vial (Entyvio)

Advance Notices
1 December 2017
Deletion – Brand
10235Q Apomine, PF – APOMORPHINE, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules
6429J APO-BOSENTAN, GX – BOSENTAN, bosentan 62.5 mg tablet, 60
6430K APO-BOSENTAN, GX – BOSENTAN, bosentan 125 mg tablet, 60

Highly Specialised Drugs Program (Public Hospital)
Additions
Addition – Item
11195F BACLOFEN, baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule (Sintetica Baclofen Intrathecal)

Addition – Note
10384M VEDOLIZUMAB, vedolizumab 300 mg injection, 1 vial (Entyvio)
Deletions

Deletion – Note

10196P INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
5754W INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
5755X INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)

Alterations

Alteration – Note

10196P INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)

Alteration – Restriction

5754W INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
10384M VEDOLIZUMAB, vedolizumab 300 mg injection, 1 vial (Entyvio)
10390W VEDOLIZUMAB, vedolizumab 300 mg injection, 1 vial (Entyvio)

Advance Notices

1 December 2017
Deletion – Brand

10227G Apomine, PF – APOMORPHINE, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules
5618Q APO-BOSENTAN, GX – BOSENTAN, bosentan 62.5 mg tablet, 60
5619R APO-BOSENTAN, GX – BOSENTAN, bosentan 125 mg tablet, 60

Highly Specialised Drugs Program (Community Access)

Advance Notices

1 December 2017
Deletion – Brand

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

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Item

4171M PARACETAMOL + CODEINE, paracetamol 500 mg + codeine phosphate 8 mg tablet, 50 (Codalgin)

Deletion – Brand

4094L Cal-Sup, IA – CALCIUM, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60
4333C Cal-Sup, IA – CALCIUM, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

Deletion – Equivalence Indicator

4094L Cal-500, PP – CALCIUM, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60
4333C Cal-500, PP – CALCIUM, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

Alterations

Alteration – Manufacturer Code

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>KY</td>
</tr>
</tbody>
</table>

| 4042R | Urederm – UREA, urea 10% cream, 100 g |

From | To |
IA | KY |
About the Schedule

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

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

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

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

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

Symbols and Abbreviations Used in the Schedule

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

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

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

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

Authority required (STREAMLINED) – authority can be sought electronically.
Guidelines and General Statements

General Statement for Lipid-Lowering Drugs

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

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

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

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

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

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

POST-DIETARY QUALIFYING CRITERIA

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

<table>
<thead>
<tr>
<th>PATIENT CATEGORY</th>
<th>LIPID LEVELS FOR PBS SUBSIDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with diabetes mellitus not otherwise included</td>
<td>total cholesterol &gt; 5.5 mmol/L</td>
</tr>
<tr>
<td>Aboriginal or Torres Strait Islander patients</td>
<td>total cholesterol &gt; 6.5 mmol/L or total cholesterol &gt; 5.5 mmol/L and HDL cholesterol &lt; 1 mmol/L</td>
</tr>
<tr>
<td>Patients with hypertension</td>
<td>total cholesterol &gt; 6.5 mmol/L</td>
</tr>
<tr>
<td>Patients with familial hypercholesterolaemia identified by:</td>
<td>If aged 18 years or less at treatment initiation: LDL cholesterol &gt; 4 mmol/L</td>
</tr>
<tr>
<td>DNA mutation; or tendon xanthomas in the patient or their first or second degree relative</td>
<td>If aged more than 18 years at treatment initiation: LDL cholesterol &gt; 5 mmol/L or total cholesterol &gt; 6.5 mmol/L or total cholesterol &gt; 5.5 mmol/L and HDL cholesterol &lt; 1 mmol/L</td>
</tr>
<tr>
<td>Patients with:</td>
<td>total cholesterol &gt; 7.5 mmol/L or triglyceride &gt; 4 mmol/L</td>
</tr>
<tr>
<td>family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives</td>
<td>total cholesterol &gt; 9 mmol/L or triglyceride &gt; 8 mmol/L</td>
</tr>
<tr>
<td>Patients not otherwise included</td>
<td>total cholesterol &gt; 7.5 mmol/L or triglyceride &gt; 4 mmol/L</td>
</tr>
<tr>
<td>Patients not otherwise included</td>
<td>total cholesterol &gt; 9 mmol/L or triglyceride &gt; 8 mmol/L</td>
</tr>
</tbody>
</table>
If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.

START HERE

Have fasting lipid levels been checked?  
No ➔ Measure fasting lipid levels
Yes ➔ Provide lifestyle and dietary prescription and/or refer for medical nutrition therapy

Has the patient received dietary therapy for at least 6 weeks?  
No ➔ Patient does not qualify for PBS subsidy
Yes ➔ Have fasting lipid levels been checked?
No ➔ Measure fasting lipid levels
Yes ➔ Assess patient against the Qualifying Criteria below
General Statement for Drugs for the Treatment of Hepatitis C

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

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

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

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

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

- the hepatitis C virus genotype; and
- the patient’s cirrhotic status (non-cirrhotic or cirrhotic)

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

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

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

**HEPATITIS C - NON-CIRRHOTIC PATIENTS**

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Naive</th>
<th>Treatment Experienced</th>
</tr>
</thead>
</table>

**KEY**

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

1. Medicines for the treatment of hepatitis C are listed for prescribing by authorised nurse practitioners under the General Schedule only. Medicines for the treatment of hepatitis C are not listed for prescribing by authorised nurse practitioners under the S100 Highly Specialised Drugs Program.
2. [LEDIPASVIR + SOFOSBUVIR] for treatment-naive, non-cirrhotic patients:
   - consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
   - otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.
3. [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR] for treatment-naive and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1b HCV.
4. [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-naive and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1a HCV.
5. [GRAZOPREVIR + ELBASVIR and RBV] for treatment-experienced, non-cirrhotic and cirrhotic patients, treatment for 16 weeks in patients with genotype 1a or 4 HCV who have experienced on-treatment virologic failure to prior treatment.
## HEPATITIS C – CIRRHOTIC PATIENTS

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Naive</th>
<th>Treatment Experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| LEDIPASVIR + SOFOSBUVIR [12 weeks]  
OR DAACLATASVIR and SOFOSBUVIR and RBV [12 weeks]  
OR DAACLATASVIR and SOFOSBUVIR [24 weeks]  
OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks]  
OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks]  
OR GRAZOPREVIR + ELBASVIR [12 weeks]  
OR SOFOSBUVIR + VELPATASVIR [12 weeks]  | LEDIPASVIR + SOFOSBUVIR [24 weeks]  
OR DAACLATASVIR and SOFOSBUVIR [24 weeks]  
OR DAACLATASVIR and SOFOSBUVIR and RBV [12 weeks]  
OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks]  
OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 or 24 weeks]  
OR GRAZOPREVIR + ELBASVIR [12 weeks]  
OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks]  
OR SOFOSBUVIR + VELPATASVIR [12 weeks]  |  |
| Genotype 2 |  |  |
| SOFOSBUVIR and RBV [12 weeks]  
OR SOFOSBUVIR + VELPATASVIR [12 weeks]  | SOFOSBUVIR and RBV [12 weeks]  
OR SOFOSBUVIR + VELPATASVIR [12 weeks]  |  |
| Genotype 3 |  |  |
| SOFOSBUVIR and RBV [24 weeks]  
OR DAACLATASVIR and SOFOSBUVIR [24 weeks]  
OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks]  
OR DAACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks]  
OR SOFOSBUVIR + VELPATASVIR [12 weeks]  | DAACLATASVIR and SOFOSBUVIR [24 weeks]  
OR SOFOSBUVIR and RBV [24 weeks]  
OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks]  
OR DAACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks]  
OR SOFOSBUVIR + VELPATASVIR [12 weeks]  |  |
| Genotype 4 |  |  |
| Genotype 5 & 6 |  |  |

**Key**

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

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6. [SOFOSBUVIR + VELPATASVIR] for patients with decompensated cirrhosis:  
   - use in combination with ribavirin.

7. [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-experienced, cirrhotic patients:  
   - consider treatment for 12 weeks in patients with genotype 1a HCV (except prior null responders to PEG-IFN and RBV) and genotype 1b HCV; or  
   - consider treatment for 24 weeks in patients with genotype 1a HCV who have had a previous null response to PEG-IFN and RBV.

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

9. [SOFOSBUVIR + VELPATASVIR] for patients with genotype 3 infection with compensated cirrhosis:  
   - consider addition of ribavirin.
Pharmaceutical Benefits Schedules
Prescriber Bag
### ADRENALINE
adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3451P</td>
<td>1</td>
<td>22.58</td>
<td>Link Medical Products Pty Ltd [LM]</td>
</tr>
</tbody>
</table>

### ATROPINE SULFATE
ATROPINE Injection 600 micrograms in 1 mL, 10

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>3453R</td>
<td>1</td>
<td>22.76</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
</tr>
</tbody>
</table>

### BENZATROPINE
benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3457Y</td>
<td>1</td>
<td>95.01</td>
<td>Cogentin [FK]</td>
</tr>
</tbody>
</table>

OR

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

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10016E</td>
<td>1</td>
<td>263.28</td>
<td>Benztropine Omega [FK]</td>
</tr>
</tbody>
</table>

### BENZYLLENICILLIN
benzylpenicillin 600 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3486L</td>
<td>5</td>
<td>*36.25</td>
<td>BenPen [CS]</td>
</tr>
</tbody>
</table>

OR

procaïne penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3485K</td>
<td>1</td>
<td>85.18</td>
<td>Cilicaine [QA]</td>
</tr>
</tbody>
</table>

### BENZYLLENICILLIN
benzylpenicillin 3 g injection, 1 vial

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3487M</td>
<td>1</td>
<td>19.78</td>
<td>BenPen [CS]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3455W</td>
<td>1</td>
<td>22.70</td>
<td>Largactil [SW]</td>
</tr>
</tbody>
</table>

OR

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

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3456X</td>
<td>1</td>
<td>24.20</td>
<td>Serenace [QA]</td>
</tr>
</tbody>
</table>

### CLONAZEPAM
clonazepam 2.5 mg/mL oral liquid, 10 mL

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3478C</td>
<td>‡1</td>
<td>14.84</td>
<td>Rivotril [RO]</td>
</tr>
</tbody>
</table>
## Dexamethasone Sodium Phosphate
**Dexamethasone Sodium Phosphate Injection** equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 ml packs

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16.36</td>
<td>&quot;Dexamethasone Mylan [AF]&quot;</td>
</tr>
</tbody>
</table>

OR

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>20.89</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

OR

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>19.85</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

## Diazepam
**Diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>17.11</td>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

## Diptheria Toxoid + Tetanus Toxoid
**Diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>136.39</td>
<td>MassBiologics tetanus and diphtheria toxoids adsorbed [CS]</td>
</tr>
</tbody>
</table>

OR

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2</td>
<td>130.13</td>
<td>ADT Booster [CS]</td>
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</tbody>
</table>

## Frusemide
**Frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>13.24</td>
<td>&quot;Frusemide-Claris [AE]&quot;</td>
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</tbody>
</table>

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

<table>
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<th>DPMQ</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>50.97</td>
<td>GlucaGen Hypokit [NO]</td>
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</table>

## Glyceryl Trinitrate
**Glyceryl trinitrate 400 microgram/actuation oral spray, 200 actuations**

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<td>‡1</td>
<td>23.01</td>
<td>Nitrolingual Pumpspray [SW]</td>
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## Hyoscine Butylibromide
**Hyoscine butylibromide 20 mg/mL injection, 5 x 1 mL ampoules**

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>25.79</td>
<td>Buscopan [VZ]</td>
</tr>
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</table>
### LIGNOCAINE
lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules

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<thead>
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<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10209H</td>
<td>1</td>
<td>36.63</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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### METHOXYFLURANE
methoxyflurane 999.9 mg/g inhalation solution, 3 mL

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<tr>
<td>3489P</td>
<td>1</td>
<td>43.26</td>
<td>Penthrax [DV]</td>
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### METOCLOPRAMIDE
metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

<table>
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<tr>
<td>3476Y</td>
<td>1</td>
<td>16.80</td>
<td>Maxolon [IA]</td>
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</table>

OR

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

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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<td>3477B</td>
<td>1</td>
<td>20.77</td>
<td>Stemetil [SW]</td>
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### MIDAZOLAM
midazolam 5 mg/mL injection, 10 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10178Q</td>
<td>1</td>
<td>39.05</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>3480E</td>
<td>1</td>
<td>23.92</td>
<td>Hospira Pty Limited [PF]</td>
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</table>

OR

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10862Q</td>
<td>1</td>
<td>20.42</td>
<td>Morphine Juno [JU]</td>
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</table>

OR

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10868B</td>
<td>1</td>
<td>23.78</td>
<td>Morphine Juno [JU]</td>
</tr>
</tbody>
</table>

OR

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

<table>
<thead>
<tr>
<th>Code</th>
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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>3479D</td>
<td>1</td>
<td>21.82</td>
<td>Hospira Pty Limited [PF]</td>
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### NALOXONE
naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10786Q</td>
<td>2</td>
<td>*153.87</td>
<td>Naloxone Hydrochloride (DBL) [PF]</td>
</tr>
</tbody>
</table>

* Naloxone Hydrochloride (DBL) [PF]  
* Naloxone Juno [JU]  

### OXYTOCIN
oxytocin 10 units/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10251M</td>
<td>1</td>
<td>61.09</td>
<td>Oxytocin Sandoz [SZ]</td>
</tr>
</tbody>
</table>
### PHYTOMENADIONE

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>24.58</td>
<td>Konakion MM [RO]</td>
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</table>

### PROMETHAZINE

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td><em>38.67</em></td>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

### SALBUTAMOL

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>14.80</td>
<td>Asmol CFC-free [AL]</td>
</tr>
<tr>
<td></td>
<td>16.07</td>
<td>Ventol CFC-free [GK]</td>
</tr>
</tbody>
</table>

**OR**

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>14.10</td>
<td>Ventol Nebules [GK]</td>
</tr>
</tbody>
</table>

**OR**

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>15.09</td>
<td>APO-Salbutamol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salbutamol Actavis [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asmol 2.5 uni-dose [AF]</td>
</tr>
<tr>
<td></td>
<td>15.30</td>
<td>Salbutamol Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**OR**

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>15.30</td>
<td>APO-Salbutamol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salbutamol Actavis [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asmol 5 uni-dose [AF]</td>
</tr>
<tr>
<td></td>
<td>15.55</td>
<td>Salbutamol Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**OR**

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>14.33</td>
<td>Ventol Nebules [GK]</td>
</tr>
</tbody>
</table>

### TRAMADOL

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>13.94</td>
<td>Tramadol ACT [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tramal 100 [CS]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tramadol Sandoz [SZ]</td>
</tr>
</tbody>
</table>

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**Schedule of Pharmaceutical Benefits – November 2017**
# General Pharmaceutical Benefits

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ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN B
amphotericin B 10 mg lozenge, 20

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<tr>
<th>Max Qty Packs</th>
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amphotericin B 10 mg lozenge, 20

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Other agents for local oral treatment

BENZYMADINE
Restricted benefit
Mucositis
Clinical criteria:
• The condition must be radiation induced.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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BENZYMADINE
Restricted benefit
Mucositis
Clinical criteria:
• The condition must be radiation induced.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

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<thead>
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<th>Max Qty Packs</th>
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DRUGS FOR ACID RELATED DISORDERS

DRUGS FOR PEPTIC ULCER AND GASTRO-oesophageal reflux disease (GORD)

H2-receptor antagonists

CIMETIDINE

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

cimetidine 400 mg tablet, 60

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FAMOTIDINE

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

famotidine 20 mg tablet, 60

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<td></td>
<td>* Famotidine AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>* GenRx Famotidine [GX]</td>
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<td>* Pepzan [ED]</td>
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famotidine 40 mg tablet, 30

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<td>* Pepzan [ED]</td>
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### Nizatidine

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

<table>
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<th>Max Qty Packs</th>
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### Ranitidine

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

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### Proton pump inhibitors

#### Esomeprazole

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

<table>
<thead>
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### ALIMENTARY TRACT AND METABOLISM

#### General Pharmaceutical Benefits

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<td>* Pharmacor Esomeprazole [CR]</td>
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**ESOMEPRAZOLE**

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

**Note Continuing Therapy Only:**

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

**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Authority required**

Scleroderma oesophagus

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**ESOMEPRAZOLE**

*Note* Helicobacter pylori eradication therapy should be considered.

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

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

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

**Restricted benefit**

Gastric ulcer

Treatment Phase: Initial treatment

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**ESOMEPRAZOLE**

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

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

**Restricted benefit**

Gastro-oesophageal reflux disease

**Clinical criteria:**

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

**Restricted benefit**

Scleroderma oesophagus
### Restricted benefit
Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

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### OMEPRAZOLE

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### OMEPRAZOLE

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

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

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

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

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### OMEPRAZOLE

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

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

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### OMEPRAZOLE

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General Pharmaceutical Benefits 31
## Omeprazole

### Omeprazole 20 mg enteric tablet, 30

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<td>1</td>
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*Acimaths [AL]*
*Omeprazole Sandoz [SZ]*
*Losec Tablets [AP]*

### Omeprazole 20 mg capsule, 30

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<td>1</td>
<td>5</td>
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*apo-omeprazole [TX]*
*omeprazole Sandoz [HX]*
*Pharmacor Omeprazole 20 [CR]*

### PANTOPRAZOLE

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

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

#### Restricted Benefit

- Peptic ulcer
- Treatment Phase: Initial treatment

### Pantoprazole 40 mg enteric tablet, 30

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*apo-pantoprazole [TX]*
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*pantoprazole [CR]*
*pantoprazole 40 [RZ]*
*pantoprazole AN [EA]*
*pantoprazole Sandoz [SZ]*
*Somac [NQ]*
*Topra 40 [DO]*

### Pantoprazole 40 mg enteric coated granules, 30 sachets

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### Pantoprazole 40 mg enteric coated granules, 30 sachets

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*apo-pantoprazole [TX]*
*ozpan [RA]*
*panto [TK]*
*pantoprazole AN [EA]*
*pantoprazole Sandoz [SZ]*
*Somac [NQ]*

### Pantoprazole 20 mg enteric tablet, 30

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<th>Max Qty Packs</th>
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*apo-pantoprazole [TX]*
*ozpan [RA]*
*panto [TK]*
*pantoprazole AN [EA]*
*pantoprazole Sandoz [SZ]*
*Somac [NQ]*

### Pantoprazole 40 mg enteric coated granules, 30 sachets

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*Somac [NQ]*
### Rabeprazole

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

#### Rabeprazole sodium 20 mg enteric tablet, 30

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<td>Razit 20 [DO]</td>
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<td>3.95</td>
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#### Rabeprazole sodium 10 mg enteric tablet, 28

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<td>Parbezo [RW]</td>
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<td></td>
<td>Rabeprazole AN [EA]</td>
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<td>Razit 20 [DO]</td>
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<td>3.95</td>
<td>18.08</td>
<td>15.34</td>
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</table>

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

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

### Esomeprazole (&) Clarithromycin (&) Amoxicillin

**Restriction benefit**
- Peptic ulcer
- Treatment Phase: Initial treatment

#### Esomeprazole sodium 20 mg enteric tablet, 30

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<td>Parbezo [RW]</td>
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<td>15.34</td>
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### Combinations for eradication of Helicobacter pylori

#### Esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack

<table>
<thead>
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<td>40.67</td>
<td>38.80</td>
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<td>ESOMEPRAZOLE SANDOZ Hp7 [SZ]</td>
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</table>

#### Esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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**Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)**
### ALIMENTARY TRACT AND METABOLISM

#### SUCRALFATE

sucralfate 1 g tablet, 120

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<tr>
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<td>26.68</td>
<td>27.89</td>
<td>Carafate [AS]</td>
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#### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

#### BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, tertiary amines

#### ATROPINE SULFATE

ATROPINE Injection 600 micrograms in 1 mL, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>22.76</td>
<td>23.97</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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</table>

*Note Shared Care Model:*

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

ATROPINE Injection 600 micrograms in 1 mL, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>22.76</td>
<td>23.97</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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#### PROPULSIVES

Propulsives

#### DOMPERIDONE

domperidone 10 mg tablet, 25

<table>
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<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>1</td>
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<td>13.13</td>
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#### METOCLOPRAMIDE

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

<table>
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<tr>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

<table>
<thead>
<tr>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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<td>..</td>
<td>..</td>
<td>16.80</td>
<td>18.01</td>
<td>Maxolon [IA]</td>
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metoclopramide hydrochloride 10 mg tablet, 25

<table>
<thead>
<tr>
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<th>No of Rpts</th>
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<td>12.22</td>
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metoclopramide hydrochloride 10 mg tablet, 25

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<td>..</td>
<td>12.22</td>
<td>13.43</td>
<td>Pramin [AF]</td>
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#### ANTIEMETICS AND ANTIINAUSEANTS

**Antiemetics and Antinauseants**

Serotonin (5HT3) antagonists

#### GRANISETRON

Restricted benefit
Nausea and vomiting
ALIMENTARY TRACT AND METABOLISM

General Pharmaceutical Benefits

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

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

### Granisetron 3 mg/3 mL injection, 3 mL ampoule

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Kytril [IX]</td>
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</table>

**GRANISETRON**

Authority required (STREAMLINED)

4092
Nausea and vomiting

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

### Granisetron 3 mg/3 mL injection, 3 mL ampoule

<table>
<thead>
<tr>
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<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
<td>Kytril [IX]</td>
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</table>

**GRANISETRON**

Authority required (STREAMLINED)

4102
Nausea and vomiting

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

### Granisetron 2 mg tablet, 5

<table>
<thead>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>Kytril [IX]</td>
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**GRANISETRON**

Restricted benefit
Nausea and vomiting

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

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

### Granisetron 2 mg tablet, 1

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<th>DPMQ $</th>
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<td>28.91</td>
<td>30.12</td>
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</table>

**NETUPITANT + PALONOSETRON**

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

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

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

**Authority required (STREAMLINED)**

5991
Nausea and vomiting

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

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

**Authority required (STREAMLINED)**

5994
Nausea and vomiting

Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND
- The treatment must be in combination with dexamethasone, AND
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.
No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6937**

Nausea and vomiting

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

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

**Authority required (STREAMLINED)**

**6879**

Nausea and vomiting

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

**ONDANSETRON**

**Authority required (STREAMLINED)**

**4102**

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with radiotherapy being used to treat malignancy.

<table>
<thead>
<tr>
<th>Ondansetron 4 mg/5 mL oral liquid, 50 mL</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Ondansetron 8 mg tablet, 10</th>
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<td><strong>Max Qty Packs</strong></td>
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<table>
<thead>
<tr>
<th>Ondansetron 8 mg/4 mL injection, 4 mL ampoule</th>
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**ONDASETRON**

**Restricted benefit**

**Nausea and vomiting**

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

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

### ondansetron 4 mg tablet, 4

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<td>12.64</td>
<td>* Ondansetron Alphapharm [AF] * Onsetron [ZP]</td>
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### ondansetron 8 mg tablet, 4

<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</table>

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

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>18.05</td>
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</table>

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

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<th>MRVSN $</th>
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<td>11.64</td>
<td>12.85</td>
<td>* Ondansetron Alphapharm [AF] * Onsetron [ZP]</td>
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### ondansetron 4 mg/5 mL oral liquid, 50 mL

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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>97.94</td>
<td>38.80</td>
<td>Zofran syrup 50 mL [AS]</td>
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</table>

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

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

### ondansetron 4 mg wafer, 4

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<tbody>
<tr>
<td>1</td>
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<td>2.45</td>
<td>17.21</td>
<td>15.97</td>
<td>* Zofran Zydis [AS]</td>
</tr>
</tbody>
</table>
### Ondansetron

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

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

#### Authority required (STREAMLINED)

5777

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with radiotherapy being used to treat malignancy.

#### Ondansetron 4 mg wafer, 10

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#### Ondansetron 8 mg wafer, 10

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#### Palonosetron

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

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

#### Palonosetron 250 microgram/5 mL injection, 5 mL vial

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#### Tropisetron

**Restricted benefit**

Nausea and vomiting

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

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
tropisetron 5 mg/5 mL injection, 5 mL ampoule

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Other antiemetics

- **APREPITANT**

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

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

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

  **Authority required (STREAMLINED)**

  **4211**
  Nausea and vomiting

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

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

  **Authority required (STREAMLINED)**

  **4215**
  Nausea and vomiting

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

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

  **Authority required (STREAMLINED)**

  **6444**
  Nausea and vomiting

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

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

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

  **Authority required (STREAMLINED)**

  **6370**
  Nausea and vomiting

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

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

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

aprepitant 165 mg capsule, 1

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- **FOSAPREPIIANT**

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

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

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

  **Authority required (STREAMLINED)**

  **6886**
  Nausea and vomiting
Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, AND
- The treatment must be in combination with a 5-hydroxytryptamine (5HT3) antagonist and dexamethasone, AND
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; Carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.
No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6891 Nausea and vomiting
Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, AND
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.
No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6887 Nausea and vomiting
Clinical criteria:
- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, AND
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, AND
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, AND
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; daclomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.
No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.
Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

Authority required (STREAMLINED)

6852 Nausea and vomiting
Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, AND
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, AND
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.
No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.
Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

fosaprepitant 150 mg injection, 1 vial

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- **PROCHLORPERAZINE**

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

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

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prochlorperazine maleate 5 mg tablet, 25

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- **PROCHLORPERAZINE**

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

Note As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.
prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules

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**PROMETHAZINE**

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

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**BILE AND LIVER THERAPY**

**BILE THERAPY**

*Bile acid preparations*

**URSODEOXYCHOLIC ACID**

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

*Note* Continuing Therapy Only:

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

**Authority required (STREAMLINED)**

5757

Primary biliary cirrhosis

ursodeoxycholic acid 500 mg tablet, 100

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ursodeoxycholic acid 250 mg capsule, 100

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**DRUGS FOR CONSTIPATION**

**DRUGS FOR CONSTIPATION**

*Contact laxatives*

**BISACODYL**

*Restricted benefit*

Constitution

*Clinical criteria:*

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

*Restricted benefit*

Constitution

*Clinical criteria:*

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

*Restricted benefit*

Constitution

*Clinical criteria:*

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

*Restricted benefit*

Constitution

*Clinical criteria:*

- Patient must be receiving palliative care.

*Restricted benefit*
ALIMENTARY TRACT AND METABOLISM

Terminal malignant neoplasia

**Restricted benefit**

Anorectal congenital abnormalities

**Restricted benefit**

Megacolon

**bisacodyl 5 mg enteric tablet, 200**

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**BISACODYL**

**Restricted benefit**

Constipation

**Clinical criteria:**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

**Clinical criteria:**
- Patient must be receiving palliative care.

**Restricted benefit**

Constipation

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

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Terminal malignant neoplasia

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Anorectal congenital abnormalities

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

Megacolon

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**bisacodyl 10 mg suppository, 10**

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**bisacodyl 10 mg suppository, 12**

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**Bulk-forming laxatives**

**RHAMNUS FRANGULA + STERCULIA**

**Restricted benefit**

Constipation

**Clinical criteria:**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

Constipation

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must be receiving palliative care.

**Restricted benefit**

**Terminal malignant neoplasia**

**Restricted benefit**

**Anorectal congenital abnormalities**

**Restricted benefit**

**Megacolon**

### Osmotically acting laxatives

#### MACROGOL-3350

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must have malignant neoplasia.

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must be receiving palliative care.

**Restricted benefit**

**Chronic constipation**

**Clinical criteria:**
• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

**Faecal impaction**

**Clinical criteria:**
• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

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

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<tr>
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<td>27.57</td>
<td>28.78</td>
<td>* Normacol Plus [NE]</td>
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**macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets**

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<td>18.66</td>
<td>19.87</td>
<td>* OsmoLax [KY]</td>
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<td>18.66</td>
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#### MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must have malignant neoplasia.

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must be receiving palliative care.

**Restricted benefit**

**Chronic constipation**

**Clinical criteria:**
• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

**Faecal impaction**

**Clinical criteria:**
• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

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

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<td>$1</td>
<td>5</td>
<td>..</td>
<td>18.66</td>
<td>19.87</td>
<td></td>
<td>* APO-MACROGOL plus ELECTROLYTES [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* LaxaCon [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Macrovic [RF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Movicol [NE]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>10126Y</th>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
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<td>..</td>
<td>*21.17</td>
<td>22.38</td>
<td></td>
<td>Movicol Liquid [NE]</td>
</tr>
</tbody>
</table>

**Enemas**

**BISACODYL**

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must be receiving palliative care.

**Restricted benefit**

**Terminal malignant neoplasia**

**Restricted benefit**

**Anorectal congenital abnormalities**

**Restricted benefit**

**Megacolon**

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

<table>
<thead>
<tr>
<th>1263L</th>
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<td>$1</td>
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<td>38.50</td>
<td>38.80</td>
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<td>Bisalax [AS]</td>
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</table>

**SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**

**Restricted benefit**

**Constipation**

**Clinical criteria:**
• Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
- Patient must be receiving palliative care.

**Restricted benefit**

**Terminal malignant neoplasia**

**Restricted benefit**

**Anorectal congenital abnormalities**

**Restricted benefit**

**Megacolon**

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

<table>
<thead>
<tr>
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<td>29.35</td>
<td>30.56</td>
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**ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS**

**INTESTINAL ANTIINFECTIVES**

**Antibiotics**

**NYSTATIN**

nystatin 500 000 units capsule, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>1699K</td>
<td>..</td>
<td>..</td>
<td>20.64</td>
<td>21.85</td>
<td>Nilstat [QA]</td>
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</table>

nystatin 500 000 units capsule, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>3345C</td>
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<td>20.64</td>
<td>21.85</td>
<td>Nilstat [QA]</td>
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</table>

nystatin 500 000 units tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>20.64</td>
<td>21.85</td>
<td>Nilstat [QA]</td>
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</table>

nystatin 500 000 units tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>3342X</td>
<td>..</td>
<td>..</td>
<td>20.64</td>
<td>21.85</td>
<td>Nilstat [QA]</td>
</tr>
</tbody>
</table>

**RIFAXIMIN**

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

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

**Authority required**

Prevention of hepatic encephalopathy

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

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

rifaximin 550 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10001J</td>
<td>5</td>
<td>..</td>
<td>490.78</td>
<td>38.80</td>
<td>Xifaxan [NE]</td>
</tr>
</tbody>
</table>

**VANCOMYCIN**

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

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**
• The condition must be due to *Clostridium difficile*, **AND**
• The condition must be unresponsive to metronidazole.

**Authority required**

Antibiotic associated pseudomembranous colitis

**Clinical criteria:**
• The condition must be due to *Clostridium difficile*, **AND**
• Patient must have an intolerance to metronidazole.

vancomycin 125 mg capsule, 20

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3113W</td>
<td></td>
<td></td>
<td>219.91</td>
<td>38.80</td>
<td>Vancocin [AS]</td>
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</tbody>
</table>

vancomycin 250 mg capsule, 20

<table>
<thead>
<tr>
<th>Max Qty</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>3114X</td>
<td></td>
<td></td>
<td>434.95</td>
<td>38.80</td>
<td>Vancocin [AS]</td>
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</tbody>
</table>

**ELECTROLYTES WITH CARBOHYDRATES**

**Oral rehydration salt formulations**

**SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**

**Authority required**

Rehydration in intestinal failure

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11049M</td>
<td></td>
<td></td>
<td>155.35</td>
<td>38.80</td>
<td>Repalyte New Formulation [SW]</td>
</tr>
</tbody>
</table>

**SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**

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

**Restricted benefit**

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

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3196F</td>
<td></td>
<td></td>
<td>15.90</td>
<td>17.11</td>
<td>O.R.S. [AS]</td>
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**ANTIPROPULSIVES**

**Antipropulsives**

**DIPHENOXYLATE + ATROPINE SULFATE**

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>2501P</td>
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<td></td>
<td>12.87</td>
<td>14.08</td>
<td>Lofenoxal [IA]</td>
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</table>

**LOPERAMIDE**

**Authority required (STREAMLINED)**

6364

Diarrhoea

**Population criteria:**
• Patient must identify as Aboriginal or Torres Strait Islander.

loperamide hydrochloride 2 mg capsule, 12

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>1571Q</td>
<td></td>
<td></td>
<td>12.58</td>
<td>13.79</td>
<td>Gastrex [CR]</td>
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**LOPERAMIDE**

**Authority required**

Diarrhoea
### INTESTINAL ANTIINFLAMMATORY AGENTS

#### Corticosteroids acting locally

##### BUDESONIDE

Note Continuing Therapy Only:

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Gastrex [CR]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*18.55</td>
<td>19.76</td>
<td></td>
</tr>
<tr>
<td>Imodium [JT]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*21.80</td>
<td>19.76</td>
<td></td>
</tr>
</tbody>
</table>

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

Note Continuing Therapy Only:

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

### HYDROCORTISONE ACETATE

Note Continuing Therapy Only:

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>Budenofalk [OA]</td>
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<td></td>
</tr>
<tr>
<td>*40.67</td>
<td>38.80</td>
<td></td>
</tr>
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</table>

** hydrocortisone acetate 10% enema, 21.1 g

Note Continuing Therapy Only:

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Colifoam [HM]</td>
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<td></td>
</tr>
<tr>
<td>*41.86</td>
<td>38.80</td>
<td></td>
</tr>
</tbody>
</table>

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

Note Continuing Therapy Only:

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

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Predsol [QA]</td>
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<tr>
<td>*198.27</td>
<td>38.80</td>
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</tr>
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</table>

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

Note Continuing Therapy Only:

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Predsol [QA]</td>
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<td></td>
</tr>
<tr>
<td>*41.86</td>
<td>38.80</td>
<td></td>
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</table>

### BALSALAZIDE

Note Not for the treatment of Crohn disease

Note Continuing Therapy Only:

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

** Authority required (STREAMLINED)

<table>
<thead>
<tr>
<th>Clinical criteria:</th>
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<tbody>
<tr>
<td>Ulcerative colitis</td>
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</tbody>
</table>
### MESALAZINE

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

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

#### Authority required (STREAMLINED)

**4824** Ulcerative colitis

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

#### mesalazine 500 mg granules, 100 sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8598M</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*273.23</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>221.60</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
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#### mesalazine 3 g granules, 30 sachets

<table>
<thead>
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<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>10257W</td>
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<td>5</td>
<td>..</td>
<td>255.73</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
</tr>
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</table>

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9353G</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*391.35</td>
<td>38.80</td>
<td>Mezavant [ZI]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8599N</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>255.73</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
</tr>
</tbody>
</table>

#### mesalazine 1.5 g granules, 60 sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>9206M</td>
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<td>255.73</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
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</tbody>
</table>

### MESALAZINE

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

#### Authority required (STREAMLINED)

**4873** Ulcerative colitis

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

#### Authority required (STREAMLINED)

**4896** Crohn disease

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

#### mesalazine 500 mg enteric tablet, 100

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8731M</td>
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<td>5</td>
<td>..</td>
<td>*273.23</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
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</tbody>
</table>
mesalazine 1 g modified release granules, 120 sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>Pentasa [FP]</td>
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</table>

mesalazine 1 g modified release tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentasa [FP]</td>
<td>287.85</td>
<td>38.80</td>
</tr>
</tbody>
</table>

mesalazine 2 g modified release granules, 60 sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentasa [FP]</td>
<td>273.23</td>
<td>38.80</td>
</tr>
</tbody>
</table>

mesalazine 500 mg modified release tablet, 100

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentasa [FP]</td>
<td>287.85</td>
<td>38.80</td>
</tr>
</tbody>
</table>

mesalazine 250 mg enteric tablet, 100

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesasal [AS]</td>
<td>86.24</td>
<td>38.80</td>
</tr>
</tbody>
</table>

**MESALAZINE**

- **Note** Not for the treatment of Crohn disease
- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note Continuing Therapy Only:**
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Acute episode of mild to moderate ulcerative proctitis

mesalazine 1 g suppository, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salofalk [OA]</td>
<td>123.34</td>
<td>38.80</td>
</tr>
</tbody>
</table>

mesalazine 1 g suppository, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentasa [FP]</td>
<td>123.34</td>
<td>38.80</td>
</tr>
</tbody>
</table>

**MESALAZINE**

- **Note** Not for the treatment of Crohn disease
- **Note** No increase in the maximum quantity or number of units may be authorised.
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**Authority required (STREAMLINED)**

4888
Acute episode of mild to moderate ulcerative colitis

mesalazine 1 g/application enema, 14 applications

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salofalk [OA]</td>
<td>*311.39</td>
<td>38.80</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salofalk [OA]</td>
<td>*311.39</td>
<td>38.80</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentasa [FP]</td>
<td>*311.39</td>
<td>38.80</td>
</tr>
</tbody>
</table>
mesalazine 4 g/60 mL enema, 7 x 60 mL

<table>
<thead>
<tr>
<th>8617M</th>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>4</td>
<td>1</td>
<td>..</td>
<td>419.19</td>
<td>38.80</td>
<td>Salofalk [OA]</td>
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</table>

**NSALAZINE**

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

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

**Authority required (STREAMLINED)**

4824
Ulcerative colitis
Clinical criteria:
- Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
- Patient must be intolerant to sulfasalazine.

olsalazine sodium 500 mg tablet, 100

<table>
<thead>
<tr>
<th>8086N</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>94.75</td>
<td>38.80</td>
<td>Dipentum [IX]</td>
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</tbody>
</table>

olsalazine sodium 250 mg capsule, 100

<table>
<thead>
<tr>
<th>1728Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>58.58</td>
<td>38.80</td>
<td>Dipentum [IX]</td>
</tr>
</tbody>
</table>

**SULFASALAZINE**

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

SULFASALAZINE Tablet 500 mg (enteric coated), 100

<table>
<thead>
<tr>
<th>2096H</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*54.43</td>
<td>38.80</td>
<td>* Pyralin EN [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>58.43</td>
<td>4.00</td>
<td>38.80</td>
<td>* Salazopyrin-EN [PF]</td>
</tr>
</tbody>
</table>

sulfasalazine 500 mg tablet, 100

<table>
<thead>
<tr>
<th>2093E</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*50.45</td>
<td>38.80</td>
<td>Salazopyrin [PF]</td>
</tr>
</tbody>
</table>

**SULFASALAZINE**

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

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

SULFASALAZINE Tablet 500 mg (enteric coated), 100

<table>
<thead>
<tr>
<th>9209Q</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>11</td>
<td>..</td>
<td>*54.30</td>
<td>38.80</td>
<td>* Pyralin EN [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>58.43</td>
<td>4.00</td>
<td>38.80</td>
<td>* Salazopyrin-EN [PF]</td>
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</table>

sulfasalazine 500 mg tablet, 100

<table>
<thead>
<tr>
<th>9208P</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>11</td>
<td>..</td>
<td>*50.45</td>
<td>38.80</td>
<td>Salazopyrin [PF]</td>
</tr>
</tbody>
</table>

**DIGESTIVES, INCL. ENZYMES**

**DIGESTIVES, INCL. ENZYMES**

**Enzyme preparations**

**PANCREATIC EXTRACT**

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

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

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

<table>
<thead>
<tr>
<th>Restriction</th>
<th>Cystic fibrosis</th>
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<tbody>
<tr>
<td>Clinical criteria:</td>
<td></td>
</tr>
<tr>
<td>• Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.</td>
<td></td>
</tr>
</tbody>
</table>

**PANCREOLIPASE**

Note Continuing Therapy Only:

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8435Y</td>
<td>5</td>
<td>1</td>
<td>240.60</td>
<td>38.80</td>
<td>NovoRapid FlexPen [NF]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8571D</td>
<td>5</td>
<td>2</td>
<td>143.15</td>
<td>38.80</td>
<td>NovoRapid [NO]</td>
</tr>
</tbody>
</table>

### INSULIN GLULISINE

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9224L</td>
<td>5</td>
<td>2</td>
<td>143.15</td>
<td>38.80</td>
<td>Apidra [SW]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1921D</td>
<td>5</td>
<td>1</td>
<td>240.60</td>
<td>38.80</td>
<td>Apidra [AV]</td>
</tr>
</tbody>
</table>

### INSULIN LISPRO

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8212F</td>
<td>5</td>
<td>1</td>
<td>240.60</td>
<td>38.80</td>
<td>Humalog [LY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8084L</td>
<td>5</td>
<td>2</td>
<td>143.15</td>
<td>38.80</td>
<td>Humalog [LY]</td>
</tr>
</tbody>
</table>

### INSULIN NEUTRAL BOVINE

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1713E</td>
<td>5</td>
<td>2</td>
<td>394.25</td>
<td>38.80</td>
<td>Hypurin Neutral [AS]</td>
</tr>
</tbody>
</table>

### INSULIN NEUTRAL HUMAN

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1762R</td>
<td>5</td>
<td>1</td>
<td>201.35</td>
<td>38.80</td>
<td>Actrapid Penfill 3 mL [NO]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1531N</td>
<td>5</td>
<td>2</td>
<td>121.10</td>
<td>38.80</td>
<td>Actrapid [NO]</td>
</tr>
</tbody>
</table>

### INSULIN ISOPHANE BOVINE

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1711C</td>
<td>5</td>
<td>2</td>
<td>394.25</td>
<td>38.80</td>
<td>Hypurin Isophane [AS]</td>
</tr>
</tbody>
</table>
### Insulins and Analogues for Injection, Intermediate- or Long-Acting Combined with Fast-Acting

#### Insulin Isophane Human

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humulin NPH [LY]</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>121.10</td>
<td>38.80</td>
</tr>
<tr>
<td>Protaphane [NO]</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

#### Insulin Aspart + Insulin Aspart Protamine

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>NovoMix 30 FlexPen [NF]</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>240.60</td>
<td>38.80</td>
</tr>
<tr>
<td>NovoMix 30 Penfill 3 mL [NO]</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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#### Insulin Neutral Human + Insulin Neutral Human

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
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<tbody>
<tr>
<td>Mixtard 50/50 Penfill 3 mL [NO]</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>201.35</td>
<td>38.80</td>
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<tr>
<td>Mixtard 30/70 InnoLet [NI]</td>
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#### Insulin Lispro + Insulin Lispro Protamine

<table>
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<tr>
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<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humalog Mix50 [LY]</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>240.60</td>
<td>38.80</td>
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<tr>
<td>Humalog Mix50 KwikPen [KP]</td>
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#### Insulin Detemir

Restricted benefit

#### Insulin Glargine

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lantus [SW]</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>406.25</td>
<td>38.80</td>
</tr>
<tr>
<td>Lantus SoloStar [AV]</td>
<td></td>
<td></td>
<td></td>
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</table>

### Blood Glucose Lowering Drugs, Excl. Insulins

#### Biguanides

#### Metformin

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Metformin XR 500 [TX]</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>15.40</td>
<td>16.61</td>
</tr>
<tr>
<td>Blooms the Chemist Metformin XR 500 [IB]</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
### ALIMENTARY TRACT AND METABOLISM

**Schedule of Pharmaceutical Benefits – November 2017**

#### General

<table>
<thead>
<tr>
<th>metformin hydrochloride 1 g modified release tablet, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3439B</strong> Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 15.40 16.61</td>
</tr>
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<td></td>
</tr>
<tr>
<td></td>
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#### General

<table>
<thead>
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<th>metformin hydrochloride 850 mg tablet, 60</th>
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</thead>
<tbody>
<tr>
<td><strong>1801T</strong> Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 13.78 14.99</td>
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#### General

<table>
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<tr>
<th>metformin hydrochloride 500 mg tablet, 100</th>
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<tbody>
<tr>
<td><strong>2430X</strong> Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
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<tr>
<td>1 5 .. 13.78 14.99</td>
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#### General

<table>
<thead>
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</thead>
<tbody>
<tr>
<td><strong>8607B</strong> Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 15.78 16.99</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Sulfonylureas**

### GLIBENCLAMIDE

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

<table>
<thead>
<tr>
<th>glibenclamide 5 mg tablet, 100</th>
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<tbody>
<tr>
<td><strong>2939Q</strong> Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 15.41 16.62</td>
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### GLICLAZIDE

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

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ALIMENTARY TRACT AND METABOLISM

GLIMEPIRIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

GLIPIZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

ALOGLIPTIN + METFORMIN

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

Authority required (STREAMLINED) 4423

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

**4427**

Diabetes mellitus type 2

Treatment Phase: Continuing

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

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

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<tr>
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### alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

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

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<td>Nesina Met 12.5/1000 [TK]</td>
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**DAPAGLIFLOZIN + METFORMIN**

Note: Continuing Therapy Only:

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

**Authority required (STREAMLINED)**

**5631**

Diabetes mellitus type 2

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

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

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

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

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

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

Note: This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5739**

Diabetes mellitus type 2

Treatment Phase: Continuing
treatment

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

Note: This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5798**

Diabetes mellitus type 2

Clinical criteria:
• The treatment must be in combination with a sulfonylurea, **AND**
• Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; **OR**
• Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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

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

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

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

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### Authority required (STREAMLINED)

5657
Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

Note This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.
Diabetes mellitus type 2

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

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

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

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

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

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

Authority required (STREAMLINED)

5966
Diabetes mellitus type 2
Treatment Phase: Continuing treatment

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

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5798
Diabetes mellitus type 2

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

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

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

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

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

Note: This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Note: PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

Diabetes mellitus type 2

Clinical criteria:
• The treatment must be in combination with insulin, AND
• Patient must have, or have had, an HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptide 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
• Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

Note: This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

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empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

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empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

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empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

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LINAGLIPTIN + METFORMIN

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

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

Authority required (STREAMLINED)

Diabetes mellitus type 2

Clinical criteria:
• Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR
• Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.
The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

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

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

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

**Authority required (STREAMLINED)**

6336  
Diabetes mellitus type 2  
Treatment Phase: Continuing  

**Clinical criteria:**

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

**Authority required (STREAMLINED)**

6344  
Diabetes mellitus type 2  

**Clinical criteria:**

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

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

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

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

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

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

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.
### METFORMIN + Glibenclamide

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

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### ROSIGLITAZONE + METFORMIN

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

**Authority required**

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have a contraindication to a sulfonylurea; OR
- Patient must not have tolerated a sulfonylurea, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying Hba1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

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

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<th>Product Description</th>
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<th>MRVSN $</th>
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SAXAGLITIN + METFORMIN

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

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

**Authority required (STREAMLINED)**

**6333**
Diabetes mellitus type 2

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

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

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

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

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

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

**Authority required (STREAMLINED)**

**6335**
Diabetes mellitus type 2

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

**Authority required (STREAMLINED)**

**6344**
Diabetes mellitus type 2

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

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

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

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

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

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

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.
saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

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

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**SITAGLIPTIN + METFORMIN**

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

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

**Authority required (STREAMLINED)**

**6333**

Diabetes mellitus type 2

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

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

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

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

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

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

**Authority required (STREAMLINED)**

**6334**

Diabetes mellitus type 2

Treatment Phase: Continuing

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

**Authority required (STREAMLINED)**

**6344**

Diabetes mellitus type 2

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

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

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

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

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

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.
**Clinical criteria:**

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

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

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

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

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

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

**Note**

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

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient’s medical records.

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

**Authoriry required (STREAMLINED) 6357**

Diabetes mellitus type 2

Treatment Phase: Continuing

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

**Authoriry required (STREAMLINED) 6344**

Diabetes mellitus type 2

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

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

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

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

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**Alpha glucosidase inhibitors**

**ACARBOSE**

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**acarbose 100 mg tablet, 90**

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**Thiazolidinediones**

**PIOGLITAZONE**

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

**Authoriry required (STREAMLINED)**
ALIMENTARY TRACT AND METABOLISM

4363
Diabetes mellitus type 2

Clinical criteria:
- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, AND
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

4388
Diabetes mellitus type 2

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

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

4364
Diabetes mellitus type 2

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

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

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)
### Dipeptidyl peptidase 4 (DPP-4) inhibitors

**ALOGLIPTIN**

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

**Authority required (STREAMLINED)**

4349

Diabetes mellitus type 2

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

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

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

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

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

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

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General Pharmaceutical Benefits 67
LINAGLIPTIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

6346
Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.
- The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

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

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

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

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

Authority required (STREAMLINED)

6363
Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with metformin, AND
- The treatment must be in combination with a sulfonylurea, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.
- The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

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

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

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

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

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

6376
Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with insulin, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.
- The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

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

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

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

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

Note

This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

linagliptin 5 mg tablet, 30

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**Note**

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

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6346**

Diabetes mellitus type 2

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

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

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

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

**Authority required (STREAMLINED)**

**6363**

Diabetes mellitus type 2

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

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

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

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

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

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

**Note**
PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### SITAGLIPTIN

**Note**
This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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

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**Authority required (STREAMLINED)**

**6346**
Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

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

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

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

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

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**Authority required (STREAMLINED)**

**6363**
Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

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

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

General Pharmaceutical Benefits

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

6376  
Diabetes mellitus type 2  

**Clinical criteria:**
- The treatment must be in combination with insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated; **OR**
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol/L in more than 20% of tests over a 2 week period prior to initiation with a glitazone, a gliptin, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

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

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9181F  
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

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9182G  
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

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**sitagliptin 25 mg tablet, 28**
9180E  
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

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**VILDAGLIPTIN**

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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

**Authority required (STREAMLINED)**

6346  
Diabetes mellitus type 2  

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

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

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

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

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a glitazone, a gluca

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

Authority required (STREAMLINED)

6363
Diabetes mellitus type 2

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

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

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

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

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

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

vildagliptin 50 mg tablet, 60

3415R

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Glucagon-like peptide-1 (GLP-1) analogues

**EXENATIDE**

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

**Note** Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6519
Diabetes mellitus type 2

Clinical criteria:
- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

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

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

Authority required (STREAMLINED)

6505
Diabetes mellitus type 2

Clinical criteria:
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
• Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
• Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

exenatide 2 mg/dose injection: modified release, 4 injection devices

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**EXENATIDE**

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or an SGLT2 inhibitor.

**Authority required (STREAMLINED)**

**5500**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

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

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

**Authority required (STREAMLINED)**

**5478**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
(b) Had red cell transfusion within the previous 3 months.
The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

5469

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with insulin, **AND**
- The treatment must be in combination with metformin unless contraindicated or not tolerated, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; **OR**
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

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

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**exenatide 10 microgram/dose injection, 60 doses**

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**Sodium-glucose co-transporter 2 (SGLT2) inhibitors**

- **DAPAGLIFLOZIN**

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

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

**Authority required (STREAMLINED)**

4983

Diabetes mellitus type 2

**Clinical criteria:**

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**
Diabetes mellitus type 2

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

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

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

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

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

**Authority required (STREAMLINED)**

Diabetes mellitus type 2

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

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

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

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

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

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.
• Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

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

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

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

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

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

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

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

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

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**Authority required (STREAMLINED)**

4983

Diabetes mellitus type 2

**Clinical criteria:**

• The treatment must be in combination with metformin; OR

• The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

4991

Diabetes mellitus type 2

**Clinical criteria:**

• The treatment must be in combination with insulin, AND

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

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

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

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

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

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

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

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

VITAMINS

VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

Vitamin D and analogues

CALCITRIOL

Authority required (STREAMLINED)

5401
Hypocalcaemia
Clinical criteria:
- The condition must be due to renal disease.

Authority required (STREAMLINED)

5255
Hypoparathyroidism

Authority required (STREAMLINED)

5089
Hypophosphataemic rickets

Authority required (STREAMLINED)

5114
Vitamin D-resistant rickets

Authority required (STREAMLINED)

5402
Established osteoporosis

Clinical criteria:
- Patient must have fracture due to minimal trauma.
  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

2502Q
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 3 .. 27.21 28.42 * APO-Calcitriol [TX]
* Calciprox [ER]
* Kosteo [RW]
* Sical [AF]

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

THIAMINE

Authority required (STREAMLINED)

5139
Thiamine deficiency

Clinical criteria:
- The treatment must be for prophylaxis.

Population criteria:
- Patient must be an Aboriginal or a Torres Strait Islander person.

thiamine hydrochloride 100 mg tablet, 100

1070H
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 .. 14.98 16.19 Betavit [PP]

MINERAL SUPPLEMENTS

CALCIUM

Calcium
**CALCIUM**

Authority required (STREAMLINED)

4586

Hyperphosphataemia

Clinical criteria:
- The condition must be associated with chronic renal failure.

**CALCIUM Tablet 600 mg (as carbonate), 240**

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**CALCIUM Tablet (chewable) 500 mg (as carbonate), 60**

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**POTASSIUM**

Potassium

**POTASSIUM CHLORIDE**

Note: For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

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**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 100**

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**POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg effervescent tablet, 60**

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**OTHER MINERAL SUPPLEMENTS**

Magnesium

**MAGNESIUM ASPARTATE DIHYDRATE**

Authority required (STREAMLINED)

5506

Hypomagnesaemia

Population criteria:
- Patient must be an Aboriginal or a Torres Strait Islander person.

**5466**

Chronic renal disease

Population criteria:
- Patient must be an Aboriginal or a Torres Strait Islander person.

**magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50**

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**ANABOLIC AGENTS FOR SYSTEMIC USE**

**ANABOLIC STEROIDS**

Estren derivatives

**NANDROLONE DECANOATE**

Note: Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.
- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

**Osteoporosis**

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- The treatment must be where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

**Authority required**

Patients receiving this drug as a pharmaceutical benefit prior to 1 February 2004

**Patients on long-term treatment with corticosteroids**

**nandrolone decanoate 50 mg/mL injection, 1 mL syringe**

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<tr>
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<td>7</td>
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<td>23.29</td>
<td>24.50</td>
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<td>Deca-Durabolin [AS]</td>
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</table>

**OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS**

**OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS**

**Amino acids and derivatives**

**BETAINE**

**Authority required**

**Homocystinuria**

**Clinical criteria:**
- The treatment must be as adjunctive therapy to current standard care, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

**betaine 1 g/g powder for oral liquid, 180 g**

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<td>$1</td>
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**Various alimentary tract and metabolism products**

**SAPROPTERIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Authority required**

**Hyperphenylalaninaemia**

**Treatment Phase: Continuing**

**Clinical criteria:**
- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously been issued with an authority prescription for this drug; OR
- Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.
sapropterin dihydrochloride 100 mg soluble tablet, 30

10087X

<table>
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<tr>
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<tr>
<td>6</td>
<td>5</td>
<td>..</td>
<td>*5309.53</td>
<td>38.80</td>
<td>Kuvan [IO]</td>
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</tbody>
</table>

Note: Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Hyperphenylalaninaemia
Treatment Phase: Initial

Clinical criteria:
• Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.
• Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

sapropterin dihydrochloride 100 mg soluble tablet, 30

10086W

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>6</td>
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<td>..</td>
<td>*5309.53</td>
<td>38.80</td>
<td>Kuvan [IO]</td>
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**BLOOD AND BLOOD FORMING ORGANS**

**ANTITHROMBOTIC AGENTS**

**Vitamin K antagonists**

**WARFARIN**

Caution: The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

warfarin sodium 5 mg tablet, 50

2211J

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>18.59</td>
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<td></td>
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<td>Marevan [FM]</td>
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warfarin sodium 3 mg tablet, 50

2844Q

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warfarin sodium 2 mg tablet, 50

2209G

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<td>..</td>
<td>16.33</td>
<td>17.54</td>
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warfarin sodium 1 mg tablet, 50

2843P

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<td>Coumadin [QA]</td>
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<td></td>
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<td>Marevan [FM]</td>
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**Heparin group**

**DALTEPARIN SODIUM**

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

8269F

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<tr>
<th>Max Qty Packs</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>84.13</td>
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<td>Fragmin [PF]</td>
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</table>

dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

8603T

<table>
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<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*95.99</td>
<td>38.80</td>
<td>Fragmin [PF]</td>
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</table>
**DALTEPARIN SODIUM**

**Restricted benefit**
Haemodialysis

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
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<td>3</td>
<td>..</td>
<td>..</td>
<td>*157.17</td>
<td>Fragmin [PF]</td>
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</tbody>
</table>

**dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>3</td>
<td>..</td>
<td>..</td>
<td>*95.99</td>
<td>Fragmin [PF]</td>
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**dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*99.99</td>
<td>Fragmin [PF]</td>
</tr>
</tbody>
</table>

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

<table>
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<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
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<td>..</td>
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**dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes**

<table>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td>*218.03</td>
<td>Fragmin [PF]</td>
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</table>

**Note** No applications for increased maximum quantities will be authorised.

**Clinical criteria:**
- Patient must have a solid tumour(s).

**dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>3</td>
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<td>..</td>
<td>*231.58</td>
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**DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>38.80</td>
<td>Fragmin [PF]</td>
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</table>

**DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10**

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*465.34</td>
<td>38.80</td>
<td>Fragmin [PF]</td>
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</tbody>
</table>

**dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*171.61</td>
<td>38.80</td>
<td>Fragmin [PF]</td>
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<tr>
<td>Brand Name and Manufacturer</td>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium</td>
<td>DPMQ</td>
<td>MRVSN</td>
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</tr>
<tr>
<td><em>Fragmin [PF]</em></td>
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<td>5</td>
<td>..</td>
<td><em>324.64</em></td>
<td>38.80</td>
</tr>
<tr>
<td><em>Clexane [SW]</em></td>
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<td>3</td>
<td>..</td>
<td><em>99.55</em></td>
<td>38.80</td>
</tr>
<tr>
<td><em>Clexane [SW]</em></td>
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<td>3</td>
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<td><em>95.99</em></td>
<td>38.80</td>
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<tr>
<td><em>Clexane [SW]</em></td>
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<td><em>Clexane [SW]</em></td>
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<td>38.80</td>
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<tr>
<td><em>Clexane [SW]</em></td>
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<td>38.80</td>
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<td><em>137.61</em></td>
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<td><em>Clexane [SW]</em></td>
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### Heparin Sodium

<table>
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<tr>
<td>Fraxiparine [AS]</td>
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<td>Fraxiparine [AS]</td>
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<td>3</td>
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<tr>
<td>Fraxiparine Forte [AS]</td>
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<td>3</td>
<td>*189.85</td>
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<td>3</td>
<td>*154.10</td>
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<tr>
<td>Fraxiparine [AS]</td>
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<td>*118.35</td>
<td>38.80</td>
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<td>*189.85</td>
<td>38.80</td>
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<tr>
<td>Fraxiparine [AS]</td>
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<td>3</td>
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</table>

**NADROPARIN**

nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>10</td>
<td>3</td>
<td>*154.05</td>
<td>38.80</td>
<td></td>
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</tbody>
</table>

nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

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<th>Premium $</th>
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<tr>
<td>10</td>
<td>3</td>
<td>*154.10</td>
<td>38.80</td>
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</tr>
</tbody>
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nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>3</td>
<td>*154.05</td>
<td>38.80</td>
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</tbody>
</table>

nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes

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<th>Premium $</th>
<th>DPMQ $</th>
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<td>10</td>
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<td>*154.05</td>
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nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
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<td>10</td>
<td>3</td>
<td>*154.05</td>
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</tbody>
</table>

nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>10</td>
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</table>

nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</tbody>
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nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
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**NADROPARIN**

nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

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nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes

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<tr>
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nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

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nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes

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nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes

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nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes

<table>
<thead>
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<th>Max.Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

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<th>DPMQ $</th>
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nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

<table>
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**Platelet aggregation inhibitors excl. heparin**

- **ABCIXIMAB**
  - **Authority required (STREAMLINED)**
  - **4942**
    - Coronary artery disease
    - **Treatment criteria:**
      - Patient must be undergoing percutaneous coronary balloon angioplasty.
  - **4943**
    - Coronary artery disease
    - **Treatment criteria:**
      - Patient must be undergoing percutaneous coronary atherectomy.
  - **4915**
    - Coronary artery disease
    - **Treatment criteria:**
      - Patient must be undergoing percutaneous coronary stent placement.

- **ASPIRIN**
  - **Restricted benefit**
  - For treatment of a patient identifying as Aboriginal or Torres Strait Islander

- **abciximab 10 mg/5 mL injection, 5 mL vial**
  - **8048N**
    - Max Qty Packs: 3
    - No. of Rpts: ..
    - Premium $: 1376.14
    - DPMQ $: 38.80
    - MRVSN $: 38.80
    - Brand Name and Manufacturer: ReoPro [JC]

- **CLOPIDOGREL**
  - **Note** Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.
  - **Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.
  - **Note Shared Care Model:**
    - For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  - **Authority required (STREAMLINED)**
  - **4166**
    - Acute coronary syndrome (myocardial infarction or unstable angina)
    - **Clinical criteria:**
      - The treatment must be in combination with aspirin.
  - **4165**
    - Cardiac stent insertion
    - **Clinical criteria:**
      - The treatment must be in combination with aspirin, **AND**
      - The treatment must follow insertion of a cardiac stent.

- **clopidogrel 75 mg tablet, 28**
  - **2275R**
    - Max Qty Packs: 1
    - No. of Rpts: 5
    - Premium $: 15.18
    - DPMQ $: 16.39
    - MRVSN $: 16.39
    - Brand Name and Manufacturer: Clopidogrel-GA [EA], Clopidogrel [RF], Clovid 75 [RW]
CLOPIDOGEREL

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

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

**Authority required (STREAMLINED)**

5517
Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:
- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

5524
Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:
- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

5525
Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:
- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

**Authority required (STREAMLINED)**

5459
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:
- Patient must have a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

5436
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:
- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

5508
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:
- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

---

clopidogrel 75 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>Blooms the Chemist Clopidogrel [IB]</td>
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<td>Clopidogrel AN [EA]</td>
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<td>Iscover [AV]</td>
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<td>Plavix [SW]</td>
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clopidogrel 75 mg tablet, 28

<table>
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<td>APO-Clopidogrel [TX]</td>
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<td>Blooms the Chemist Clopidogrel [IB]</td>
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<td>Iscover [AV]</td>
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<td>Plavix [SW]</td>
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<td>Terry White Chemists Clopidogrel [TW]</td>
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clopidogrel 75 mg tablet, 28

<table>
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<td>* Clopidogrel-GA [EA]</td>
<td>* Clopidogrel GH [GQ]</td>
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<td>* Clovid 75 [RW]</td>
<td>* Plidogrel [RF]</td>
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</tbody>
</table>

**CLOPIDOGREL + ASPIRIN**

*Note* Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

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

**Authority required (STREAMLINED)**

5488
Acute coronary syndrome (myocardial infarction or unstable angina)

**Authority required (STREAMLINED)**

5443
Cardiac stent insertion

**Clinical criteria:**
- The treatment must follow insertion of a cardiac stent.

**Authority required (STREAMLINED)**

5517
Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**
- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

*Note* Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

clopidogrel 75 mg + aspirin 100 mg tablet, 30

<table>
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<td>* Chem mart Clopidogrel/Aspirin 75/100 [CH]</td>
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<td>* Clopidogrel/Aspirin Sandoz 75/100 [SZ]</td>
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<td></td>
<td></td>
<td></td>
<td>* Clopidogrel Winthrop plus aspirin [WA]</td>
<td>* CoFlavix [SW]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td>* DuoCover [AV]</td>
<td>*  DuoPlidogrel [GZ]</td>
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<td>* Piax Plus Aspirin [AF]</td>
<td>* Terry White Chemists Clopidogrel/Aspirin 75/100 [TW]</td>
</tr>
</tbody>
</table>

**DIPYRIDAMOLE**

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

**Restricted benefit**
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**
- The treatment must be as adjunctive therapy with low-dose aspirin.

**Restricted benefit**
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**
- Patient must be one in whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Restricted benefit**
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**
- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

dipyridamole 200 mg modified release capsule, 60

<table>
<thead>
<tr>
<th>8335Q</th>
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<th>No. of Rpts</th>
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<tr>
<td>1</td>
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<td>36.32</td>
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<td>Persantin SR [BY]</td>
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**EPTIFIBATIDE**

**Authority required (STREAMLINED)**

**6435**

Coronary artery disease

**Treatment criteria:**
- Patient must be undergoing non-urgent percutaneous intervention with intracoronary stenting.

<table>
<thead>
<tr>
<th>Eptifibatide 20 mg/10 mL injection, 10 mL vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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</table>

**PRASUGREL**

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

**Authority required (STREAMLINED)**

**6454**

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**
- The treatment must be managed by percutaneous coronary intervention in combination with aspirin.

<table>
<thead>
<tr>
<th>Prasugrel 5 mg tablet, 28</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Prasugrel 10 mg tablet, 28</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**TICAGRELOR**

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

**Authority required (STREAMLINED)**

**5746**

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**
- The treatment must be in combination with aspirin.

**Ticagrelor Tablet 90 mg, 56**

<table>
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**TIROFIBAN**

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

**Authority required (STREAMLINED)**

**5782**

High risk of unstable angina

**Clinical criteria:**
- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.
BLOOD AND BLOOD FORMING ORGANS

Authority required (STREAMLINED)
5809
High risk of unstable angina
Clinical criteria:
• Patient must have new transient or persistent ST-T ischaemic changes, AND
• Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

Authority required (STREAMLINED)
5691
Non-Q-wave myocardial infarction

Tirofiban 12.5 mg/50 mL injection, 50 mL vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>Tirofib AC [JO]</td>
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</table>

Enzymes

■ RETEPLASE

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

Restricted benefit
Acute myocardial infarction
Clinical criteria:
• The treatment must be administered within 6 hours of the onset of attack.

Replase 10 units (17.4 mg) injection [2 x 10 unit vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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■ TENECTEPLASE

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

Restricted benefit
Acute myocardial infarction
Clinical criteria:
• The treatment must be administered within 12 hours of onset of attack.

Tenecteplase 10 000 units (50 mg) injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack

<table>
<thead>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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Tenecteplase 8000 units (40 mg) injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack

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Direct thrombin inhibitors

■ BIVALIRUDIN

Authority required (STREAMLINED)
4919
Coronary artery disease
Treatment criteria:
• Patient must be undergoing percutaneous coronary intervention.

Bivalirudin 250 mg injection, 1 vial

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■ DABIGATRAN

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

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

Authority required (STREAMLINED)
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 60**

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**dabigatran etexilate 110 mg capsule, 60**

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**DABIGATRAN**

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

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

**Authority required (STREAMLINED)**

**4369**
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 20 days supply to complete a course of treatment.

**dabigatran etexilate 110 mg capsule, 10**

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**DABIGATRAN**

- **Note:** No increase in the maximum quantity or number of units may be authorised.
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**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4381**
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 10 days of therapy.

**dabigatran etexilate 110 mg capsule, 10**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**DABIGATRAN**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

4269
Prevention of stroke or systemic embolism

**Clinical criteria:**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
1. Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
2. Age 75 years or older;
3. Hypertension;
4. Diabetes mellitus;
5. Heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 150 mg capsule, 60**

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**dabigatran etexilate 110 mg capsule, 60**

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**Direct factor Xa inhibitors**

**APIXABAN**

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

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

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

**Authority required (STREAMLINED)**

4402
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 60**

<table>
<thead>
<tr>
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**APIXABAN**

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

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

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

**Authority required (STREAMLINED)**

4098
Deep vein thrombosis

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

5098
Pulmonary embolism

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have confirmed acute symptomatic pulmonary embolism.
### APIXABAN

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

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

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

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**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 15 days of therapy.

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**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 15 days supply to complete a course of treatment.

### APIXABAN

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</table>
• Patient must have non-valvular atrial fibrillation, **AND**
• Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

4132
Prevention of recurrent venous thromboembolism
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

<table>
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**APIXABAN**

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

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

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

**Authority required (STREAMLINED)**

4269
Prevention of stroke or systemic embolism

**Clinical criteria:**
• Patient must have non-valvular atrial fibrillation, **AND**
• Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

4099
Deep vein thrombosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
• Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

5083
Pulmonary embolism
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

<table>
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**RIVAROXABAN**

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

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

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

**Authority required (STREAMLINED)**

4369
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 20 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 10**

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**Note**
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**Note**
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**Note Shared Care Model:**
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**Authority required (STREAMLINED)**

4402
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 15**

<table>
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**RIVAROXABAN Tablet 10 mg, 30**

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**Note**
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**Note**
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**Note Shared Care Model:**
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**Authority required (STREAMLINED)**

4381
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 10 days of therapy.

**rivaroxaban 10 mg tablet, 10**

<table>
<thead>
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**Note**
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**Note**
No increase in the maximum number of repeats may be authorised.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
• Patient must be undergoing total knee replacement.
Clinical criteria:
• Patient must require up to 15 days of therapy.

**rivaroxaban 10 mg tablet, 15**

<table>
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### RIVAROXABAN

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

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

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

Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4269**
Prevention of stroke or systemic embolism

Clinical criteria:
• Patient must have non-valvular atrial fibrillation, **AND**
• Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

### rivaroxaban 15 mg tablet, 28

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### RIVAROXABAN

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

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

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

**Authority required (STREAMLINED)**

**4098**
Deep vein thrombosis
Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
• Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**4260**
Pulmonary embolism
Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have confirmed acute symptomatic pulmonary embolism.

Note Special Pricing Arrangements apply.

### rivaroxaban 15 mg tablet, 42

<table>
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<tbody>
<tr>
<td>2160Q</td>
<td>1</td>
<td>..</td>
<td>125.21</td>
<td>38.80</td>
<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>
BLOOD AND BLOOD FORMING ORGANS

**Authority required (STREAMLINED) 4099**

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority required (STREAMLINED) 4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED) 4268**

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**Note**
Special Pricing Arrangements apply.

**Authority required (STREAMLINED) 4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

**Risk factors for developing stroke or systemic ischaemic embolism are:**
- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note**
Special Pricing Arrangements apply.

rivaroxaban 20 mg tablet, 28

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>87.17</td>
<td>Xarelto [BN]</td>
</tr>
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</table>

**Other antithrombotic agents**

- **FONDAPARINUX**

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

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

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

**Authority required (STREAMLINED) 5781**

Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing major hip surgery.

**Authority required (STREAMLINED) 5808**

Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total knee replacement.

FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2

<table>
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**ANTIHEMORRHAGICS**

**ANTIFIBRINOLYTICS**

**Amino acids**
**TRANEXAMIC ACID**

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

<table>
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<tr>
<th>tranexamic acid 500 mg tablet, 100</th>
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**ANTIEMETIC PREPARATIONS**

**IRON PREPARATIONS**

Iron bivalent, oral preparations

**FERROUS FUMARATE**

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

<table>
<thead>
<tr>
<th>ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60</th>
</tr>
</thead>
<tbody>
<tr>
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**FERROUS SULFATE**

ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL

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<th>ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL</th>
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Iron, parenteral preparations

**IRON**

iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial

<table>
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<th>iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial</th>
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<td>10104T</td>
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**IRON POLYMALTOSE**

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

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**IRON POLYMALTOSE**

Authority required (STREAMLINED)

<table>
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<tr>
<td>2018J</td>
</tr>
<tr>
<td>5302</td>
</tr>
<tr>
<td>*</td>
</tr>
<tr>
<td>• Patient must be undergoing chronic haemodialysis.</td>
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<table>
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<th>iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules</th>
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**IRON SUCROSE**

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

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<th>iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules</th>
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**IRON SUCROSE**

Authority required (STREAMLINED)

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<td>5302</td>
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<tr>
<td>*</td>
</tr>
<tr>
<td>• Patient must be undergoing chronic haemodialysis.</td>
</tr>
</tbody>
</table>
iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

- **Iron in combination with folic acid**

## FERROUS FUMARATE + FOLIC ACID

### Restricted benefit

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

ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60

## VITAMIN B12 AND FOLIC ACID

### Hydroxocobalamin

- **Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

- **Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

### Restricted benefit

- Pernicious anaemia
- **Population criteria:**
  - Patient must identify as Aboriginal or Torres Strait Islander.

- Proven vitamin B12 deficiencies other than pernicious anaemia
- **Population criteria:**
  - Patient must identify as Aboriginal or Torres Strait Islander.

- Anaemias associated with vitamin B12 deficiency
- **Clinical criteria:**
  - Patient must have had a gastrectomy, AND
  - The treatment must be for prophylaxis.
- **Population criteria:**
  - Patient must identify as Aboriginal or Torres Strait Islander.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

- **Restricted benefit**
- **Brand Name and Manufacturer:**

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

### Folic acid and derivatives

## FOLIC ACID

### Restricted benefit

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

folic acid 500 microgram tablet, 100

- **Note** The 5 mg strength tablet should be used in malabsorption states only.

### Restricted benefit

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

folic acid 5 mg tablet, 100
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

PENTASTARCH + SODIUM CHLORIDE
HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1

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<tr>
<td>9487H</td>
<td>3</td>
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<td>44.17</td>
<td>38.80</td>
<td>Voluven 6% [PK]</td>
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SUCCYNLATED GELATIN
succinylated gelatin 20 g/500 mL injection, 500 mL bag

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<td>44.17</td>
<td>38.80</td>
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OTHER HEMATOLOGICAL AGENTS

ICATIBANT
Note Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

Authority required
Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial
Clinical criteria:
- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, AND
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, AND
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.
The name of the specialist consulted must be provided at the time of application for initial supply.
The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Authority required
Anticipated emergency treatment of an acute attack of hereditary angioedema
Treatment Phase: Continuing
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug.

ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>1976B</td>
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<td>2574.52</td>
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<td>Firazyr [ZI]</td>
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</table>

CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

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

digoxin 62.5 microgram tablet, 200

<table>
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<tr>
<td>2605D</td>
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<td>14.57</td>
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<tr>
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<td>2.56</td>
<td>17.13</td>
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*Slight variation
digoxin 250 microgram tablet, 100
1322N
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. 14.82 16.03 Sigmaxin [FM]
2.56 17.38 16.03 Lamoxin [QA]

digoxin 50 microgram/mL oral liquid, 60 mL
3164M
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 3 .. 41.29 38.80 Lanoxin [QA]

ANTIARRHYTHMICS, CLASS I AND III

Antiarrhythmics, class Ia

DISOPYRAMIDE
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
disopyramide 100 mg capsule, 100
2923W
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 29.85 31.06 Rythmodan [SW]

LIGNOCaine
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules
2876J
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 3 .. 30.23 31.44 Xylocard 500 [AS]

Antiarrhythmics, class Ib

FLECAInIDE
Caution Flecainide acetate should be avoided in patients with poor cardiac function.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Serious supra-ventricular cardiac arrhythmias
Restricted benefit
Serious ventricular cardiac arrhythmias
Clinical criteria:
• The treatment must be initiated in a hospital.
flecainide acetate 50 mg tablet, 60
1088G
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 33.97 35.18 Flecainide Sandoz [SZ] Tambocor [IA]
flecainide acetate 100 mg tablet, 60
1090J
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 39.45 38.80 Flecainide Sandoz [SZ] Tambocor [IA] Flecatab [AF]

Antiarrhythmics, class III

AMIODARONE
Note This drug has been reported to cause frequent and potentially serious toxicity.
Note Regular monitoring of hepatic and thyroid function is recommended.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Severe cardiac arrhythmias
amiodarone hydrochloride 200 mg tablet, 30

<table>
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<tr>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
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<td>..</td>
<td>18.83</td>
<td>20.04</td>
<td>* Amiodarone Sandoz [SZ]</td>
<td>* Aratac 200 [AF]</td>
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<td></td>
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<td></td>
<td></td>
<td>* Cordarone X 200 [SW]</td>
<td>* GenRx Amiodarone [GX]</td>
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<td></td>
<td></td>
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<td>* Rithmik 200 [RW]</td>
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amiodarone hydrochloride 100 mg tablet, 30

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<tr>
<td>1</td>
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<td>..</td>
<td>15.44</td>
<td>16.65</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cordarone X 100 [SW]</td>
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</table>

**SOTALOL**

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

**Restricted benefit**
Severe cardiac arrhythmias

sotalol hydrochloride 160 mg tablet, 60

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<td>19.21</td>
<td>* APO-Sotalol [TX]</td>
<td>* Cardol [AF]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Solavert [RF]</td>
<td>* Sotalol Sandoz [SZ]</td>
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<td>4.33</td>
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sotalol hydrochloride 80 mg tablet, 60

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<td></td>
<td>* Solavert [RF]</td>
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**CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES**

*Adrenergic and dopaminergic agents*

**ADRENALINE**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>..</td>
<td>22.58</td>
<td>23.79</td>
<td>Link Medical Products Pty Ltd [LM]</td>
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</table>

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

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>..</td>
<td></td>
<td>22.58</td>
<td>23.79</td>
<td>Link Medical Products Pty Ltd [LM]</td>
</tr>
</tbody>
</table>

**ADRENALINE**

*Caution* EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

*Note* The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

*Note* Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

*Note* No applications for repeats will be authorised.

**Authority required**
Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**
Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**
• Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

• Patient must have previously been issued with an authority prescription for this drug.

### Adrenaline 150 microgram/0.3 mL injection, 1 dose

<table>
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</table>

### Adrenaline 300 microgram/0.3 mL injection, 1 dose

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<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium</th>
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<td>EpiPen [AL]</td>
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### Vasodilators Used in Cardiac Diseases

**Organic nitrates**

#### Glyceryl Trinitrate

- glyceryl trinitrate 5 mg/24 hours patch, 30
  - 1515R
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | ..          | 27.31    | 28.52|       | Transiderm-Nitro 25 [SZ]    |
- glyceryl trinitrate 5 mg/24 hours patch, 30
  - 8010N
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | ..          | 27.31    | 28.52|       | Nitro-Dur 5 [MK]             |
- glyceryl trinitrate 5 mg/24 hours patch, 30
  - 8027L
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | ..          | 27.31    | 28.52|       | Minitran 5 [IA]              |
- glyceryl trinitrate 300 microgram sublingual tablet, 100
  - 11027J
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | ‡1            | 5           | 18.40    | 19.61|       | Nitrostat [PF]              |
- glyceryl trinitrate 300 microgram sublingual tablet, 100
  - 11051P
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | ‡1            | ..          | 18.40    | 19.61|       | Nitrostat [PF]              |
- glyceryl trinitrate 15 mg/24 hours patch, 30
  - 8026K
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | 5           | 32.36    | 33.57|       | Nitro-Dur 15 [MK]            |
- glyceryl trinitrate 15 mg/24 hours patch, 30
  - 8119H
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | 5           | 32.36    | 33.57|       | Minitran 15 [IA]             |
- glyceryl trinitrate 10 mg/24 hours patch, 30
  - 1516T
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | 5           | 32.36    | 33.57|       | Transiderm-Nitro 50 [SZ]     |
- glyceryl trinitrate 10 mg/24 hours patch, 30
  - 8011P
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | 5           | 32.36    | 33.57|       | Nitro-Dur 10 [MK]            |
- glyceryl trinitrate 10 mg/24 hours patch, 30
  - 8028M
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | =             | 5           | 32.36    | 33.57|       | Minitran 10 [IA]             |
- glyceryl trinitrate 600 microgram sublingual tablet, 100
  - 1459T
    | Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer |
    | ‡1            | 5           | 18.40    | 19.61|       | Nitrostat [PF]              |

* Lycinate [RF]
CARDIOVASCULAR SYSTEM

## Glyceryl trinitrate 600 microgram sublingual tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5108W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;2.56 20.96 19.61 * Anginine Stabilised [RW]</td>
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</tbody>
</table>

## Glyceryl trinitrate 400 microgram/actuation oral spray, 200 actuations

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8171C</td>
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<td>&quot;2.56 20.96 19.61 * Anginine Stabilised [RW]</td>
</tr>
</tbody>
</table>

## ISOSORBIDE DINITRATE

### Isosorbide dinitrate 5 mg sublingual tablet, 100

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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2588F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;18.40 20.96 19.61 * Anginine Stabilised [RW]</td>
</tr>
</tbody>
</table>

## ISOSORBIDE MONONITRATE

### Isosorbide mononitrate 120 mg modified release tablet, 30

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8273K</td>
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<td></td>
<td></td>
<td></td>
<td>&quot;18.41 20.96 19.62 * Monodur 120 mg [PM]</td>
</tr>
</tbody>
</table>

### Isosorbide mononitrate 60 mg modified release tablet, 30

<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1558B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;14.77 15.98 15.98 * Monodur 60 mg [PM]</td>
</tr>
</tbody>
</table>

## Other vasodilators used in cardiac diseases

### NICORANDIL

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

### Nicorandil 10 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8228C</td>
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<td></td>
<td></td>
<td>&quot;2.48 17.25 15.98 * Monodur Durule [AP]</td>
</tr>
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</table>

### Nicorandil 20 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8229D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;3.37 18.14 15.98 * Monodur Durule [AP]</td>
</tr>
</tbody>
</table>

### PERHEXILINE

Note Regular monitoring of drug serum levels is recommended.

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

Authority required (STREAMLINED)

5592

Angina

Clinical criteria:
- The condition must not be responding to other therapy.
OTHER CARDIAC PREPARATIONS

Other cardiac preparations

**IVABRADINE**

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

**Authority required (STREAMLINED)**

4979

Chronic heart failure

**Clinical criteria:**
- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 7.5 mg tablet, 56**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2960T</td>
<td>5</td>
<td>..</td>
<td>56.25</td>
<td>38.80</td>
<td>Coralan [SE]</td>
</tr>
</tbody>
</table>

**ivabradine 5 mg tablet, 56**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10012Y</td>
<td>5</td>
<td>..</td>
<td>56.25</td>
<td>38.80</td>
<td>Coralan [SE]</td>
</tr>
</tbody>
</table>

**ANTIADRENERGIC AGENTS, CENTRALLY ACTING**

**Methyldopa**

**METHYLDOPA**

methyldopa 250 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1629R</td>
<td>5</td>
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<td>19.89</td>
<td>21.10</td>
<td>Hydopa [AF]</td>
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</table>

**Imidazoline receptor agonists**

**CLONIDINE**

clonidine hydrochloride 150 microgram tablet, 100

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3141H</td>
<td>5</td>
<td>..</td>
<td>32.62</td>
<td>33.83</td>
<td>Catapres [BY]</td>
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</table>

clonidine hydrochloride 100 microgram tablet, 100

<table>
<thead>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3145M</td>
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<td>26.67</td>
<td>27.88</td>
<td>APO-Clonidine [TX]</td>
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</table>

**MOXONIDINE**

**Restricted benefit**

Hypertension

**Clinical criteria:**
- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9019Q</td>
<td>5</td>
<td>..</td>
<td>21.92</td>
<td>23.13</td>
<td>Physiotens [GO]</td>
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</tbody>
</table>
### Cardiovascular System

#### Antiadrenergic Agents, Peripherally Acting

**Alpha-adrenoreceptor antagonists**

### Prazosin

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<th>Prazosin 1 mg tablet, 100</th>
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<tbody>
<tr>
<td><strong>1479W</strong></td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1</td>
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<tr>
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<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Prazosin 5 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1478T</strong></td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
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<td>1</td>
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### Arteriolar Smooth Muscle, Agents Acting on

#### Hydralazine

<table>
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<tr>
<th>Hydralazine Hydrochloride 25 mg tablet, 100</th>
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</thead>
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<td><strong>1640H</strong></td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
<td>2</td>
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</table>

<table>
<thead>
<tr>
<th>Hydralazine Hydrochloride 50 mg tablet, 100</th>
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<tbody>
<tr>
<td><strong>1639G</strong></td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<td>2</td>
</tr>
</tbody>
</table>

### Minoxidil

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

#### Restricted benefit
- Severe refractory hypertension

**Clinical criteria:**
- The treatment must be initiated by a consultant physician.

<table>
<thead>
<tr>
<th>Minoxidil 10 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2313R</strong></td>
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<tr>
<td>Max Qty Packs</td>
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### Diuretics

#### Low-Ceiling Diuretics, Thiazides

**Thiazides, plain**

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<th>Hydrochlorothiazide 25 mg tablet, 100</th>
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<tbody>
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### Sulfonamides, plain
### CHLORTHALIDONE

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<tr>
<td>1585K</td>
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<td>20.29</td>
<td>Hygroton 25 [GH]</td>
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### INDAPAMIDE

#### indapamide hemihydrate 2.5 mg tablet, 90

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>2436F</td>
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<td>16.37</td>
<td>* Dapa-Tabs [AF]</td>
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<td></td>
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<td>* Indapamide AN [EA]</td>
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<td>* Insig [RW]</td>
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<td>20.76</td>
<td>* GenRx Indapamide [GX]</td>
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<td>* Indapamide Sandoz [SZ]</td>
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#### indapamide hemihydrate 1.5 mg modified release tablet, 90

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<td>18.80</td>
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<td>* INDAPAMIDE AN SR [EA]</td>
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<td>* Tenaxil SR [RW]</td>
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<td>* Odaplx SR [AF]</td>
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<td></td>
<td>* Terry White Chemists</td>
</tr>
<tr>
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<td>20.01</td>
<td>* Indapamide SR [TW]</td>
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</table>

### HIGH-CEILING DIURETICS

#### Sulfonamides, plain

### FRUSEMIDE

#### frusemide 500 mg tablet, 50

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2415D</td>
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<td>3</td>
<td>..</td>
<td>18.92</td>
<td>Urex-Forte [RW]</td>
</tr>
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</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2413B</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>13.24</td>
<td>* Frusemide-Claris [AE]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>* Frusax [ER]</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>14.45</td>
<td>* Chem mart Frusemide [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Frusumide RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* FUROSEMIDE AN [EA]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Uremide [AF]</td>
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#### frusemide 40 mg tablet, 100

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2412Y</td>
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<td>1</td>
<td>..</td>
<td>12.77</td>
<td>Urex [RW]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Frusemide [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Frusumide Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14.62</td>
<td>* Chem mart Frusemide [CH]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Frusumide RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13.98</td>
<td>* FUROSEMIDE AN [EA]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Uremide [AF]</td>
</tr>
</tbody>
</table>

#### frusemide 10 mg/mL oral liquid, 30 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2411X</td>
<td>1†</td>
<td>3</td>
<td>..</td>
<td>27.11</td>
<td>Lasix [SW]</td>
</tr>
</tbody>
</table>

### FRUSEMIDE

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

#### frusemide 20 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2414C</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>12.77</td>
<td>* APO-Frusemide [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Frusumide RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13.98</td>
<td>* Chem mart Frusemide [CH]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* FUROSEMIDE AN [EA]</td>
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#### frusemide 20 mg tablet, 50

<table>
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<th>Max Qty Packs</th>
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<tr>
<td>1810G</td>
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<td>Urex-M [RW]</td>
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<td></td>
<td></td>
<td>13.98</td>
<td>* Lasix-M [SW]</td>
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</table>
ETHACRYNIC ACID

Restricted benefit
Patients hypersensitive to other oral diuretics

ethacrynic acid 25 mg tablet, 100

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>8748K</td>
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<td>*175.93</td>
<td>38.80</td>
<td>Edecrin [FK]</td>
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</table>

POTASSIUM-SPARING AGENTS

Aldosterone antagonists

EPLERENONE

Caution Serum electrolytes should be checked regularly

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

Authority required (STREAMLINED)
4937
Heart failure with a left ventricular ejection fraction of 40% or less
Clinical criteria:
• The condition must occur within 3 to 14 days following an acute myocardial infarction, AND
• The treatment must be commenced within 14 days of an acute myocardial infarction.
The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

eplerenone 25 mg tablet, 30

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>8879H</td>
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<td>88.24</td>
<td>38.80</td>
<td>Eplerenone AN [EA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inplera [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Espler [RW]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Inspria [PF]</td>
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</table>

eplerenone 50 mg tablet, 30

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<td></td>
<td>Inplera [AF]</td>
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<tr>
<td></td>
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<td></td>
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<td>Espler [RW]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Inspria [PF]</td>
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</tbody>
</table>

SPIRONOLACTONE

Caution Serum electrolytes should be checked regularly
Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

spironolactone 100 mg tablet, 100

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<td>30.83</td>
<td>32.04</td>
<td>Spiraact 100 [AF]</td>
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<tr>
<td></td>
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<td>Aldactone [PF]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Moduretic [AS]</td>
</tr>
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<td></td>
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<td>Hydrelactone [PK]</td>
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spironolactone 25 mg tablet, 100

<table>
<thead>
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<tr>
<td>2339D</td>
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<td>5</td>
<td>16.11</td>
<td>17.32</td>
<td>Spiraact 25 [AF]</td>
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<td>Aldactone [PF]</td>
</tr>
<tr>
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<td></td>
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<td>Moduretic [AS]</td>
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<tr>
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<td></td>
<td>Hydrelactone [PK]</td>
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</table>

DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

Low-ceiling diuretics and potassium-sparing agents

AMILORIDE + HYDROCHLOROTHIAZIDE

Caution Serum electrolytes should be checked regularly.

amiloride hydrochloride 5 mg + hydrochlorothiazide 50 mg tablet, 50

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>1486F</td>
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<td>1</td>
<td>*17.25</td>
<td>18.46</td>
<td>Moduretic [AS]</td>
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</table>

HYDROCHLOROTHIAZIDE + TRIAMTERENE

Caution Serum electrolytes should be checked regularly.

hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100

<table>
<thead>
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<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>1280J</td>
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<td>1</td>
<td>16.72</td>
<td>17.93</td>
<td>Hydrene 25/50 [AF]</td>
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## PERIPHERAL VASODILATORS

### PHENOXYBENZAMINE

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

**Restricted benefit**
Phaeochromocytoma

**Restricted benefit**
Neurogenic urinary retention

<table>
<thead>
<tr>
<th>Formula</th>
<th>Description</th>
<th>MaxQty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 30</td>
<td></td>
<td>1166J</td>
<td>3</td>
<td>5</td>
<td>*997.75</td>
<td>38.80</td>
<td>Amdipharm Mercury (Australia) Pty Limited [GH]</td>
</tr>
<tr>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 100</td>
<td></td>
<td>1862B</td>
<td>1</td>
<td>5</td>
<td>1103.27</td>
<td>38.80</td>
<td>Dibenzyline [GH]</td>
</tr>
<tr>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 100</td>
<td></td>
<td>9286R</td>
<td>1</td>
<td>5</td>
<td>1103.27</td>
<td>38.80</td>
<td>Dibenzyline [BZ]</td>
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## BETA BLOCKING AGENTS

### OXPRENOLOL

<table>
<thead>
<tr>
<th>Formula</th>
<th>Description</th>
<th>MaxQty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>oxprenolol hydrochloride 40 mg tablet, 100</td>
<td></td>
<td>2961W</td>
<td>1</td>
<td>5</td>
<td>46.54</td>
<td>38.80</td>
<td>Corbeton 40 [AF]</td>
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### PINDOLOL

<table>
<thead>
<tr>
<th>Formula</th>
<th>Description</th>
<th>MaxQty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>pindolol 5 mg tablet, 100</td>
<td></td>
<td>3062E</td>
<td>1</td>
<td>5</td>
<td>31.97</td>
<td>33.18</td>
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### PROPRANOLOL

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| propranolol hydrochloride 10 mg tablet, 100 | | 2565B | 1 | 5 | 13.84 | 15.05 | * APO-Propranolol [TX] |*
| propranolol hydrochloride 10 mg tablet, 100 | | 2566C | 1 | 5 | 14.11 | 15.32 | * APO-Propranolol [TX] |*
| propranolol hydrochloride 40 mg tablet, 100 | | 2565B | 1 | 5 | 16.83 | 15.05 | * Deralin 10 [AF] |*
| propranolol hydrochloride 40 mg tablet, 100 | | 2566C | 1 | 5 | 17.10 | 15.32 | * Deralin 40 [AF] |*
| propranolol hydrochloride 160 mg tablet, 50 | | 2899N | 1 | 5 | 17.81 | 19.02 | Deralin 160 [AF] |* 

*Beta blocking agents, selective
### ATENOLOL

<table>
<thead>
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<th>Schedule of Pharmaceutical Benefits – November 2017</th>
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<tbody>
<tr>
<td><strong>ATENOLOL</strong></td>
</tr>
<tr>
<td>atenolol 50 mg tablet, 30</td>
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</tr>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1</td>
</tr>
<tr>
<td>* APO-Atenolol [TX]</td>
</tr>
<tr>
<td>* Atenolol-GA [ED]</td>
</tr>
<tr>
<td>* Atenolol RBX [RA]</td>
</tr>
<tr>
<td>* Chem mart Atenolol [CH]</td>
</tr>
<tr>
<td>* Tenolten 50 [DO]</td>
</tr>
<tr>
<td>* Terry White Chemists Atenol [TW]</td>
</tr>
<tr>
<td><strong>ATENOLOL</strong></td>
</tr>
<tr>
<td>Restricted benefit</td>
</tr>
<tr>
<td>For a patient who is unable to take a solid dose form of atenolol.</td>
</tr>
<tr>
<td>atenolol 50 mg/10 mL oral liquid, 300 mL</td>
</tr>
<tr>
<td>2243C</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1‡</td>
</tr>
<tr>
<td>* Atenol-AFT [AE]</td>
</tr>
<tr>
<td><strong>BISOPROLOL</strong></td>
</tr>
<tr>
<td>Note Continuing Therapy Only:</td>
</tr>
<tr>
<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
</tr>
<tr>
<td>Restricted benefit</td>
</tr>
<tr>
<td>Moderate to severe heart failure</td>
</tr>
<tr>
<td><strong>BISOPROLOL</strong></td>
</tr>
<tr>
<td><strong>bisoprolol fumarate 5 mg tablet, 28</strong></td>
</tr>
<tr>
<td>8605X</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>* APO-Bisoprol [TX]</td>
</tr>
<tr>
<td>* Bicard 5 [RW]</td>
</tr>
<tr>
<td>* Bisoprol generichealth [GQ]</td>
</tr>
<tr>
<td>* Bispro 5 [AF]</td>
</tr>
<tr>
<td>* Terry White Chemists Bisoprol [TW]</td>
</tr>
<tr>
<td><strong>bisoprolol fumarate 2.5 mg tablet, 28</strong></td>
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<td>8604W</td>
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<tr>
<td>Max Qty Packs</td>
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</tr>
<tr>
<td>* APO-Bisoprol [TX]</td>
</tr>
<tr>
<td>* Bicard 2.5 [RW]</td>
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<td>* Bisoprol generichealth [GQ]</td>
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<tr>
<td>* Bispro 2.5 [AF]</td>
</tr>
<tr>
<td>* Terry White Chemists Bisoprol [TW]</td>
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<tr>
<td><strong>bisoprolol fumarate 10 mg tablet, 28</strong></td>
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<td>Max Qty Packs</td>
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<tr>
<td>* APO-Bisoprol [TX]</td>
</tr>
<tr>
<td>* Bicard 10 [RW]</td>
</tr>
<tr>
<td>* Bisoprol generichealth [GQ]</td>
</tr>
<tr>
<td>* Bispro 10 [AF]</td>
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<td>* Terry White Chemists Bisoprol [TW]</td>
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<td><strong>METOPROLOL SUCCINATE</strong></td>
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<td>Note Continuing Therapy Only:</td>
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<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
</tr>
<tr>
<td>Restricted benefit</td>
</tr>
<tr>
<td>Moderate to severe heart failure</td>
</tr>
</tbody>
</table>
Clinical criteria:
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8732N</td>
<td>1</td>
<td>..</td>
<td>19.35</td>
<td>20.56</td>
<td>* Metrol-XL 23.75 [RW]</td>
<td>* Minax XL [AF]</td>
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<td></td>
<td></td>
<td>* Toprol-XL 23.75 [AP]</td>
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**METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>8734Q</td>
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<td>5</td>
<td>59.80</td>
<td>38.80</td>
<td>* Metrol-XL 95 [RW]</td>
<td>* Minax XL [AF]</td>
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<td></td>
<td></td>
<td></td>
<td>* Toprol-XL 95 [AP]</td>
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**METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>8735R</td>
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<td>5</td>
<td>71.97</td>
<td>38.80</td>
<td>* Metrol-XL 190 [RW]</td>
<td>* Minax XL [AF]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Toprol-XL 190 [AP]</td>
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**METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>8733P</td>
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<td>5</td>
<td>50.07</td>
<td>38.80</td>
<td>* Metrol-XL 47.5 [RW]</td>
<td>* Minax XL [AF]</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Toprol-XL 47.5 [AP]</td>
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**METOPROLOL TARTRATE**

**METOPROLOL TARTRATE Tablet 50 mg, 100**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td>* Mistrom [ER]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>b APO-Metoprolol [TX]</td>
<td>b Chem mart Metoprolol [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>b Metoprolol Sandoz [SZ]</td>
<td>b Metrol 100 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>b Minax 50 [AF]</td>
<td>b Terry White Chemists</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Metoprolol [TW]</td>
</tr>
</tbody>
</table>

**NEBIVOLOL**

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

Restricted benefit
- Moderate to severe heart failure

Clinical criteria:
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9316H</td>
<td>2</td>
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<td>*48.81</td>
<td>38.80</td>
<td>Nebilet [FK]</td>
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**nebivolol 10 mg tablet, 28**

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<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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GENERAL

**nebivolol 5 mg tablet, 28**

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<td>38.80</td>
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**Alpha and beta blocking agents**

- **CARVEDILOL**

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

  **Restricted benefit**
  Moderate to severe heart failure
  **Clinical criteria:**
  - Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

  **Restricted benefit**
  Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

- **carvedilol 25 mg tablet, 60**

<table>
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<tr>
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<th>No. of Rpts</th>
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<td>Terry White Chemists</td>
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<td>Carvedilol 25 mg [TW]</td>
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- **carvedilol 12.5 mg tablet, 60**

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- **carvedilol 3.125 mg tablet, 30**

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- **carvedilol 6.25 mg tablet, 60**

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- **LABETALOL**

- **labetalol hydrochloride 100 mg tablet, 100**

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- **labetalol hydrochloride 200 mg tablet, 100**

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Schedule of Pharmaceutical Benefits – November 2017
### CARDIOVASCULAR SYSTEM

#### SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

*Dihydropyridine derivatives*

##### AMLODIPINE

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<th>Amlo 10 mg tablet, 30</th>
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<td>Ozlodip [RA]</td>
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<table>
<thead>
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<tr>
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<td>Amlodipine GH [GQ]</td>
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<td>Ozlodip [RA]</td>
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##### FELODIPINE

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##### LERCANIDIPINE

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<td>Chem mart Lercanidipine [CH]</td>
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<td>Chem mart Lercanidipine [CH]</td>
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</tbody>
</table>
CARDIOVASCULAR SYSTEM

**NIFEDIPINE**

- **nifedipine 20 mg tablet, 60**
  - 1695F
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 17.23
  - DPMQ $: 18.44
  - MRVSN $: 19.52
  - Brand Name and Manufacturer: Adefin 20 [AF]

- **nifedipine 10 mg tablet, 60**
  - 1694E
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 16.08
  - DPMQ $: 17.29
  - MRVSN $: 18.33
  - Brand Name and Manufacturer: Adefin 10 [AF]

- **nifedipine 60 mg modified release tablet, 30**
  - 1907J
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 19.75
  - DPMQ $: 20.96
  - MRVSN $: 22.41
  - Brand Name and Manufacturer: Cordilox 180 SR [GT]

- **nifedipine 30 mg modified release tablet, 30**
  - 1906H
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 17.98
  - DPMQ $: 19.19
  - MRVSN $: 20.50
  - Brand Name and Manufacturer: Cardizem CD [SW]

**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS**

*Phenylalkylamine derivatives*

- **VERAPAMIL**
  - Caution: The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

- **verapamil hydrochloride 180 mg modified release tablet, 30**
  - 2208F
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 17.12
  - DPMQ $: 18.33
  - MRVSN $: 20.62
  - Brand Name and Manufacturer: Cordilox 180 SR [GT]

- **verapamil hydrochloride 40 mg tablet, 100**
  - 1248Q
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 15.96
  - DPMQ $: 17.17
  - Brand Name and Manufacturer: Adefin 20 [AF]

- **verapamil hydrochloride 80 mg tablet, 100**
  - 1250T
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 18.56
  - DPMQ $: 19.77
  - Brand Name and Manufacturer: Adefin 80 [AF]

- **verapamil hydrochloride 240 mg modified release tablet, 30**
  - 1241H
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 20.18
  - DPMQ $: 21.39
  - Brand Name and Manufacturer: Diltiazem Sandoz CD [SZ]

* Benzothiazepine derivatives

- **DILTIAZEM**
  - Caution: The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

- **diltiazem hydrochloride 240 mg modified release capsule, 30**
  - 1313D
  - Max Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 20.18
  - DPMQ $: 21.39
  - Brand Name and Manufacturer: Diltiazem Sandoz CD [SZ]
diltiazem hydrochloride 360 mg modified release capsule, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 23.00 24.21 * Diltiazem Sandoz [SZ] * Vasocardol CD [AV]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 17.81 19.02 * Diltiazem Sandoz [SZ] * Vasocardol CD [AV]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

ACE INHIBITORS, PLAIN

ACE inhibitors, plain

CASTOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

captopril 50 mg tablet, 90

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 20.65 21.86 * Captopril Sandoz [SZ]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 14.44 15.65 * Captopril Sandoz [SZ]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 15.94 17.15 * Captopril Sandoz [SZ]

Restricted benefit

Patients unable to take a solid dose form of an ACE inhibitor.

captopril 12.5 mg tablet, 90

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 20.08 21.86 * Zedace [AF]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 17.87 15.65 * Zedace [AF]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 19.37 15.65 * Zedace [AF]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 20.61 17.15 * Capoten [RW]

ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

enalapril maleate 10 mg tablet, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 14.18 15.39 * Acetec [AL] * APO-Enalapril [TX]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 15.01 16.22 * Acetec [AL] * APO-Enalapril [TX]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 15.54 15.39 * Renitec [MK]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 20.37 16.22 * Renitec 20 [MK]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 19.54 15.39 * Renitec [MK]

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 20.61 17.15 * Malean [RW]
## Enalapril Maleate 5 mg Tablet, 30

<table>
<thead>
<tr>
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<th>MRVSN $</th>
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<td>Enalapril Actavis [ED]</td>
<td>Enalapril generichealth [GQ]</td>
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<td></td>
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<td>Enalapril Sandoz [SZ]</td>
<td>Malean [RW]</td>
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### Fosinopril

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

## Fosinopril Sodium 20 mg Tablet, 30

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<tr>
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## Fosinopril Sodium 10 mg Tablet, 30

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<td>Monace 10 [AF]</td>
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</table>

### Lisinopril

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

## Lisinopril 10 mg Tablet, 30

<table>
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<tr>
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<td>Fibsol 10 [RW]</td>
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<td></td>
<td>Lisinopril AN [EA]</td>
<td>Terry White Chemists</td>
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<td></td>
<td>Lisinopril Sandoz [SZ]</td>
<td>Lisinopril [TW]</td>
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<td></td>
<td>Zinopril 10 [AL]</td>
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<tr>
<td>B</td>
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<td>17.63</td>
<td>15.54</td>
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<td>Zestril [AP]</td>
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## Lisinopril 20 mg Tablet, 30

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<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
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<td>Fibsol 20 [RW]</td>
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<td>Terry White Chemists</td>
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<td>Lisinopril Sandoz [SZ]</td>
<td>Lisinopril [TW]</td>
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## Lisinopril 5 mg Tablet, 30

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<th>MRVSN $</th>
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<tr>
<td></td>
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<td>Chem mart Lisinopril [CH]</td>
<td>Fibsol 5 [RW]</td>
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<tr>
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<td>Lisinopril AN [EA]</td>
<td>Terry White Chemists</td>
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<tr>
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<td></td>
<td>Lisinopril Sandoz [SZ]</td>
<td>Lisinopril [TW]</td>
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<td>Zinopril 5 [AL]</td>
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<td>Zestril [AP]</td>
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</table>

### Perindopril

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

## Perindopril Erbumine 2 mg Tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>Idaprex 2 [SZ]</td>
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<td></td>
<td>Indosyl Mono 2 [RW]</td>
<td>Perindo [AF]</td>
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<td></td>
<td></td>
<td>Perindopril Actavis 2 [EA]</td>
<td>Perindopril AN [EF]</td>
</tr>
</tbody>
</table>
### Perindopril

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

### Quinapril

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### Ramipril

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.
### RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

#### ramipril 1.25 mg capsule, 30

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<th>Max Qty</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
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<tr>
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<td>..</td>
<td>12.11</td>
<td>13.32</td>
<td>APO-Ramipril [TX]</td>
<td>Chem mart Ramipril [CH]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ramace 10 mg [AV]</td>
<td>Ramipril Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ramipril generichealth [GQ]</td>
<td>Ramipril Winthrop [WA]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>Tritec 10 mg [SW]</td>
<td>Tryzan Tabs 1.25 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vascalace Caps 1.25 [DO]</td>
<td></td>
</tr>
</tbody>
</table>

#### ramipril 1.25 mg tablet, 30

<table>
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<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>5</td>
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<td>13.32</td>
<td>Ramace 1.25 mg [AV]</td>
<td>Chem mart Ramipril [CH]</td>
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<td>Ramipril Winthrop [WA]</td>
<td>Ramipril Sandoz [SZ]</td>
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<td>Tryzan Tabs 1.25 [AF]</td>
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</table>

### RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

#### ramipril 2.5 mg capsule, 30

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<td>Chem mart Ramipril [CH]</td>
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<td>Ramipril generichealth [GQ]</td>
<td>Ramipril Winthrop [WA]</td>
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<td></td>
<td></td>
<td>Tritec 2.5 mg [SW]</td>
<td>Tryzan Caps 2.5 [AF]</td>
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<td></td>
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<td>Vascalace Caps 2.5 [DO]</td>
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#### ramipril 2.5 mg tablet, 30

<table>
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<td>Tritec 2.5 mg [SW]</td>
<td>Tryzan Caps 2.5 [AF]</td>
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<td>Vascalace Caps 2.5 [DO]</td>
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</table>

### RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.
### CARDIOVASCULAR SYSTEM

#### ACE INHIBITORS, COMBINATIONS

##### ACE inhibitors and diuretics

**TRANDOLAPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>Dolapril 4 [RW]</td>
<td>Tranalpha [AF]</td>
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<td>Gopten [GO]</td>
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</table>

**FOSINOPRIL + HYDROCHLOROTHIAZIDE**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<td>APO-Fosinopril HCTZ 20/12.5 [TX]</td>
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<td>APO-Fosinopril/HCT Actavis 20/12.5 [EA]</td>
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### PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>2190G</td>
<td>1</td>
<td>13.07</td>
<td>14.28</td>
<td>* PREXUM Combi LD 2.5/0.625 [RW]</td>
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<td></td>
<td>4.19</td>
<td>17.26</td>
<td>14.28</td>
<td>* Coversyl Plus LD 2.5mg/0.625mg [SE]</td>
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</table>

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

### Restricted benefit

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; **OR**
- The condition must be inadequately controlled with a thiazide-like diuretic.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>2.51</td>
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<td>16.04</td>
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<td>4.21</td>
<td>19.04</td>
<td>16.04</td>
<td>* Idaprex Combi 4/1.25 [SZ]</td>
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<tr>
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<td>4/2.51</td>
<td>17.34</td>
<td>16.04</td>
<td>* Indosyl Combi 4/1.25 [RW]</td>
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<td>4/2.51</td>
<td>17.34</td>
<td>16.04</td>
<td>* Perindopril and Indapamide AN 4/1.25 [EF]</td>
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<td>4/2.51</td>
<td>17.34</td>
<td>16.04</td>
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</tr>
<tr>
<td></td>
<td>*</td>
<td>19.04</td>
<td>16.04</td>
<td>* Perindo Combi 4/1.25 [AF]</td>
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</table>

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2845R</td>
<td>1</td>
<td>16.92</td>
<td>18.13</td>
<td>Accuretic 10/12.5mg [PF]</td>
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</tr>
<tr>
<td></td>
<td>4.21</td>
<td>19.04</td>
<td>16.04</td>
<td>* Prexum Combi 5/1.25 [RW]</td>
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</tr>
<tr>
<td></td>
<td>4/2.51</td>
<td>17.34</td>
<td>16.04</td>
<td>* Coversyl Plus 5mg/1.25mg [SE]</td>
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</table>

### QUINAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8589C</td>
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<td>16.92</td>
<td>18.13</td>
<td>Accuretic 10/12.5mg [PF]</td>
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**quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

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<td>8590D</td>
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<td>17.85</td>
<td>19.06</td>
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</table>

### ACE inhibitors and calcium channel blockers

### LERCANIDIPINE + ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; **OR**
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.
PERINDOPRIL + AMLODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:
- The treatment must not be for the initiation of anti-hypertensive therapy, AND
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease

Clinical criteria:
- The treatment must not be for the initiation of therapy for coronary heart disease, AND
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

RAMIPRIL + FELODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:
- The treatment must not be for the initiation of anti-hypertensive therapy, AND
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

TRANODAPRIL + VERAPAMIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

Restricted benefit
**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; **OR**
- The condition must be inadequately controlled with verapamil.

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

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**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

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**ANGIOTENSIN II ANTAGONISTS, PLAIN**

**Angiotensin II antagonists, plain**

- **Candesartan**
  - **candesartan cilexetil 16 mg tablet, 30**
    | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer         |
    |---------------|------------|-----------|--------|---------|-----------------------------------|
    | 8297Q         | 5          | ..        | 15.22  | 16.43   | *Adesan [AF]*                      |
    |               |            |           |        |         | *Auro-Candesartan 16 [DO]*         |
    |               |            |           |        |         | *CANDESAN [RF]*                    |
    |               |            |           |        |         | *Candesartan Aspen 16 [RW]*        |
    |               |            |           |        |         | *Candesartan Sandoz [SZ]*          |
    |               |            |           |        |         | *Terry White Chemists Candesartan [TW]* |
    |               |            |           |        |         | *APO-Candesartan [TX]*             |
    |               |            |           |        |         | *Bloms the Chemist Candesartan [IB]* |
    |               |            |           |        |         | *Candesartan AN [EA]*              |
    |               |            |           |        |         | *Candesartan GH [GQ]*              |
    |               |            |           |        |         | *Chem mart Candesartan [CH]*       |

- **candesartan cilexetil 4 mg tablet, 30**
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>8295N</td>
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<td>..</td>
<td>11.55</td>
<td>12.76</td>
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<tr>
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<td></td>
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<td><em>Auro-Candesartan 4 [DO]</em></td>
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<td></td>
<td></td>
<td></td>
<td><em>CANDESAN [RF]</em></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td><em>Candesartan Aspen 4 [RW]</em></td>
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<td></td>
<td><em>Candesartan Sandoz [SZ]</em></td>
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<td></td>
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- **candesartan cilexetil 32 mg tablet, 30**
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<th>MRVSN $</th>
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<td>..</td>
<td>16.08</td>
<td>17.29</td>
<td><em>Adesan [AF]</em></td>
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<tr>
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<td><em>Auro-Candesartan 32 [DO]</em></td>
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<td><em>CANDESAN [RF]</em></td>
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<td><em>Candesartan Aspen 32 [RW]</em></td>
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- **candesartan cilexetil 8 mg tablet, 30**
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<tr>
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<td></td>
<td><em>Auro-Candesartan 8 [DO]</em></td>
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<td></td>
<td></td>
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<td></td>
<td><em>CANDESAN [RF]</em></td>
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<td></td>
<td></td>
<td><em>Candesartan Aspen 8 [RW]</em></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><em>Chem mart Candesartan [CH]</em></td>
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</table>

- **Candesartan**
  - **candesartan cilexetil 4 mg tablet, 30**
    | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer         |
    |---------------|------------|-----------|--------|---------|-----------------------------------|
    | 8295N         | 5          | ..        | 11.55  | 12.76   | *Adesan [AF]*                      |
    |               |            |           |        |         | *Auro-Candesartan 4 [DO]*          |
    |               |            |           |        |         | *CANDESAN [RF]*                    |
    |               |            |           |        |         | *Candesartan Aspen 4 [RW]*         |
    |               |            |           |        |         | *Candesartan Sandoz [SZ]*          |
    |               |            |           |        |         | *Terry White Chemists Candesartan [TW]* |

- **candesartan cilexetil 32 mg tablet, 30**
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8889W</td>
<td>5</td>
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<td>16.08</td>
<td>17.29</td>
<td><em>Adesan [AF]</em></td>
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<td></td>
<td><em>CANDESAN [RF]</em></td>
</tr>
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<td></td>
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<td></td>
<td><em>Candesartan Aspen 32 [RW]</em></td>
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<td></td>
<td><em>Candesartan Sandoz [SZ]</em></td>
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<td></td>
<td><em>Terry White Chemists Candesartan [TW]</em></td>
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- **candesartan cilexetil 8 mg tablet, 30**
<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8296P</td>
<td>5</td>
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<td>12.48</td>
<td>13.69</td>
<td><em>Adesan [AF]</em></td>
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<td><em>Auro-Candesartan 8 [DO]</em></td>
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<td></td>
<td><em>CANDESAN [RF]</em></td>
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<td></td>
<td><em>Candesartan Aspen 8 [RW]</em></td>
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<td><em>Chem mart Candesartan [CH]</em></td>
</tr>
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</table>
### EPROSARTAN

**Eprosartan 600 mg tablet, 28**

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<tr>
<td>1</td>
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**Eprosartan 400 mg tablet, 28**

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<tr>
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</table>

### Authority required

- Adverse effects occurring with all of the base-priced drugs
- Drug interactions occurring with all of the base-priced drugs
- Drug interactions expected to occur with all of the base-priced drugs
- Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

**Eprosartan 600 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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**Eprosartan 400 mg tablet, 28**

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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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### IRBESARTAN

**Irbesartan 150 mg tablet, 30**

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<th>Brand Name and Manufacturer</th>
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<tr>
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<td><em>Blooms the Chemist Irbesartan [IB]</em></td>
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<td></td>
<td><em>Irbesartan Actavis 150 [ED]</em></td>
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<td><em>Irbesartan AN [EA]</em></td>
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<td><em>Irbesartan RBX [RA]</em></td>
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<td><em>Irpresan 150 [ZP]</em></td>
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<td><em>Avapro [AV]</em></td>
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<td><em>Karvea [SW]</em></td>
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**Irbesartan 75 mg tablet, 30**

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<td><em>Blooms the Chemist Irbesartan [IB]</em></td>
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<td><em>Irbesartan AN [EA]</em></td>
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<td><em>Irbesartan Sandoz [SZ]</em></td>
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<td><em>Karvea [SW]</em></td>
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**Irbesartan 300 mg tablet, 30**

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<td></td>
<td><em>Blooms the Chemist Irbesartan [IB]</em></td>
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<td>15.99</td>
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<td><em>Karvea [SW]</em></td>
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## CARDIOVASCULAR SYSTEM

### LOSARTAN

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### OLMESARTAN MEDOXOMIL

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### TELMISARTAN

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### VALSARTAN

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### Valsartan

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

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### Angiotensin II Antagonists, Combinations

**Angiotensin II antagonists and diuretics**

#### Candesartan + Hydrochlorothiazide

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a thiazide diuretic.

<table>
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<tr>
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### EPROSARTAN + HYDROCHLOROTHIAZIDE
#### Restricted benefit
**Hypertension**

#### Clinical criteria:
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a thiazide diuretic.

**eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28**

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### IRBESARTAN + HYDROCHLOROTHIAZIDE
#### Restricted benefit
**Hypertension**

#### Clinical criteria:
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a thiazide diuretic.

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

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<td>Irbesartan HCT GH 300/25 [GQ]</td>
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<td>Irbesartan HCTZ AMNEAL [EF]</td>
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<td>Irbesartan/HCTZ RBX 300/25 [RA]</td>
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<td>Terry White Chemists Irbesartan HCTZ [TW]</td>
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<td>1.70</td>
<td>17.00</td>
<td>* Avapro HCT 300/25 [AV]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Karvezide 300/25 [SW]</td>
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**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

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<th>No. of Rpts</th>
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<td>Irbesartan HCT GH 300/12.5 [GQ]</td>
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<td>Irbesartan HCTZ AMNEAL [EF]</td>
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<td>* Karvezide 300/12.5 [SW]</td>
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**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

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<td>* Karvezide 150/12.5 [SW]</td>
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### OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE
#### Restricted benefit
**Hypertension**

#### Clinical criteria:
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

### olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

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<td>Olmertan COMBI 40/25 [RW]</td>
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<td>Olmesartan HCT - MYL 40/25 [AF]</td>
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<td>Olmetec Plus [MK]</td>
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### olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

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<td>Olmesartan HCT - MYL 40/12.5 [AF]</td>
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<td>Olmesartan/HCT Sandoz [SZ]</td>
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### olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

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<td>Olmesartan/HCT Sandoz [SZ]</td>
<td>Olmetec Plus [MK]</td>
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#### TEMLISARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a thiazide diuretic.

### telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

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<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<td>Telmisartan/HCT Sandoz [SZ]</td>
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<td>Micardis Plus 40/12.5 mg [BY]</td>
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### telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

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### telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

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<td>Telmisartan/HCT Sandoz [SZ]</td>
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#### VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

**Hypertension**
CARDIOVASCULAR SYSTEM

Clinical criteria:
• The treatment must not be for the initiation of anti-hypertensive therapy, AND
• The condition must be inadequately controlled with an angiotensin II antagonist; OR
• The condition must be inadequately controlled with a thiazide diuretic.

valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>* Co-Diovan 80/12.5 [NV]</td>
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valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>* Dilart HCT 160/25 [AF]</td>
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VALSARTAN + HYDROCHLOROTHIAZIDE

Note: No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

Restricted benefit
Hypertension
Clinical criteria:
• The treatment must not be for the initiation of anti-hypertensive therapy, AND
• The condition must be inadequately controlled with an angiotensin II antagonist; OR
• The condition must be inadequately controlled with a thiazide diuretic.

valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

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Angiotensin II antagonists and calcium channel blockers

AMLODIPINE + VALSARTAN

Restricted benefit
Hypertension
Clinical criteria:
• The treatment must not be for the initiation of anti-hypertensive therapy, AND
• The condition must be inadequately controlled with an angiotensin II antagonist; OR
• The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

amldipine 10 mg + valsartan 160 mg tablet, 28

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amldipine 5 mg + valsartan 320 mg tablet, 28

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CARDIOVASCULAR SYSTEM

amlodipine 5 mg + valsartan 160 mg tablet, 28
9376L

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amlodipine 10 mg + valsartan 320 mg tablet, 28
5460J

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- **OLMESARTAN MEDOXOMIL + AMLODIPINE**
  
  **Restricted benefit**
  
  **Hypertension**
  
  **Clinical criteria:**
  - The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
  - The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
  - The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30
5292M

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olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30
5294P

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olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30
5293N

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- **TELMISARTAN + AMLODIPINE**
  
  **Restricted benefit**
  
  **Hypertension**
  
  **Clinical criteria:**
  - The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
  - The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
  - The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

telmisartan 80 mg + amlodipine 5 mg tablet, 28
8980P

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Angiotensin II antagonists, other combinations

- **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**
  
  **Restricted benefit**
  
  **Hypertension**
  
  **Clinical criteria:**
  - The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
  - The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.
Cardiovascular System

amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 30.25 31.46 Exforge HCT 10/320/25 [NV]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 27.02 28.23 Exforge HCT 10/160/25 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 24.86 26.07 Exforge HCT 5/160/12.5 [NV] Valsartan/Amlodipine/HCT Sandoz 160/5/12.5 [NM]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 25.51 26.72 Exforge HCT 10/160/12.5 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 26.38 27.59 Exforge HCT 5/160/25 [NV]

Omesartan + Amlodipine + Hydrochlorothiazide

Restricted benefit
Hypertension
Clinical criteria:
- The treatment must not be for the initiation of anti-hypertensive therapy, AND
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

Omesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 32.60 33.81 Sevikar HCT 40/5/25 [MK]

Omesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 21.81 23.02 Sevikar HCT 20/5/12.5 [MK]

Omesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 33.29 34.50 Sevikar HCT 40/10/25 [MK]

Omesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 30.77 31.98 Sevikar HCT 40/5/12.5 [MK]

Omesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 31.45 32.66 Sevikar HCT 40/10/12.5 [MK]

Sacubitril + Valsartan

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6915 Chronic heart failure

Clinical criteria:
- Patient must be symptomatic with NYHA classes II, III or IV, AND
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, AND
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated, AND
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

- **LIPID MODIFYING AGENTS**

- **LIPID MODIFYING AGENTS, PLAIN**

- **HMG CoA reductase inhibitors**

- **ATORVASTATIN**

  **Restricted benefit**

  For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

  - **atorvastatin 10 mg tablet, 30**
    - 8213G
    - Max Qty: 1
    - No of Rpts: 5
    - Premium $: 12.62
    - DPMQ $: 13.83
    - Brand Name and Manufacturer: APO-Atorvastatin [TX]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin SCP 10 [RZ]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Blooms the Chemist Atorvastatin [IB]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]

  - **atorvastatin 40 mg tablet, 30**
    - 8215J
    - Max Qty: 1
    - No of Rpts: 5
    - Premium $: 14.26
    - DPMQ $: 15.47
    - Brand Name and Manufacturer: APO-Atorvastatin [TX]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin SCP 40 [RZ]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Blooms the Chemist Atorvastatin [IB]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
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    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]

  - **atorvastatin 80 mg tablet, 30**
    - 8521L
    - Max Qty: 1
    - No of Rpts: 5
    - Premium $: 15.63
    - DPMQ $: 16.84
    - Brand Name and Manufacturer: APO-Atorvastatin [TX]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin SCP 80 [RZ]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Blooms the Chemist Atorvastatin [IB]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
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    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]

  - **atorvastatin 20 mg tablet, 30**
    - 8214H
    - Max Qty: 1
    - No of Rpts: 5
    - Premium $: 13.35
    - DPMQ $: 14.56
    - Brand Name and Manufacturer: APO-Atorvastatin [TX]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin SCP 20 [RZ]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Blooms the Chemist Atorvastatin [IB]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
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    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
    - Brand Name and Manufacturer: Atorvastatin Amneal [EF]
    - Brand Name and Manufacturer: Atorvastatin Sandoz [SZ]
CARDIOVASCULAR SYSTEM

ATORVASTATIN

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

Restricted benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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

atorvastatin 10 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>APO-Atorvastatin [TX]</td>
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<td>Chem mart Atorvastatin [CH]</td>
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<td>Lipitor [PF]</td>
<td>Atorvastatin 10 [AF]</td>
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atorvastatin 40 mg tablet, 30

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atorvastatin 80 mg tablet, 30

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atorvastatin 20 mg tablet, 30

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FLUVASTATIN

Restricted benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

fluvastatin 80 mg modified release tablet, 28

<table>
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Schedule of Pharmaceutical Benefits – November 2017
FLUVASTATIN

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

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

Reserved benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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

fluvastatin 80 mg modified release tablet, 28

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PRAVASTATIN

Reserved benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

pravastatin sodium 20 mg tablet, 30

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pravastatin sodium 10 mg tablet, 30

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pravastatin sodium 80 mg tablet, 30

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pravastatin sodium 40 mg tablet, 30

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PRAVASTATIN

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

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

Reserved benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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

pravastatin sodium 20 mg tablet, 30

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### PRVASTATIN

**Pravastatin sodium 10 mg tablet, 30**

max. qty packs: 9237E  No. of rpts: 1 premium: 11 DPMQ: 16.49 MRVSN: 14.74 brand name and manufacturer: APO-Pravastatin (TX) CHEM MERT PRVA (CH) CHOLSTAT 20 (AF) PRVASTATIN AN (EA) PRVASTATIN SANDOZ (SZ) TERRY WHITE CHEMISTS Prepavastatin (TW)

**Pravastatin sodium 80 mg tablet, 30**

max. qty packs: 9240H  No. of rpts: 1 premium: 11 DPMQ: 15.57 MRVSN: 13.84 brand name and manufacturer: APO-Pravastatin (TX) CHEM MERT PRVA (CH) CHOLSTAT 80 (AF) PRVASTATIN AN (EA) PRVASTATIN SANDOZ (SZ) TERRY WHITE CHEMISTS Prepavastatin (TW)

**Pravastatin sodium 40 mg tablet, 30**

max. qty packs: 9239G  No. of rpts: 1 premium: 11 DPMQ: 15.58 MRVSN: 13.84 brand name and manufacturer: APO-Pravastatin (TX) CHEM MERT PRVA (CH) CHOLSTAT 40 (AF) PRVASTATIN AN (EA) PRVASTATIN SANDOZ (SZ) TERRY WHITE CHEMISTS Prepavastatin (TW)

### ROSUVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Rosuvastatin 20 mg tablet, 30**

max. qty packs: 2574L  No. of rpts: 1 premium: 5 DPMQ: 18.95 MRVSN: 16.10 brand name and manufacturer: APO-Rosuvastatin (TX) APPZUVA 20 (ZP) FRETON (AP) ROSUVASTATIN AMNEAL (EF) ROSUVASTATIN DRLA (RI) TERRY WHITE CHEMISTS Prepavastatin (TW)

**Rosuvastatin 5 mg tablet, 30**

max. qty packs: 2606E  No. of rpts: 1 premium: 5 DPMQ: 16.85 MRVSN: 14.06 brand name and manufacturer: APO-Rosuvastatin (TX) APPZUVA 5 (ZP) FRETON (AP) ROSUVASTATIN AMNEAL (EF) ROSUVASTATIN DRLA (RI) TERRY WHITE CHEMISTS Prepavastatin (TW)

**Rosuvastatin 10 mg tablet, 30**

max. qty packs: 2628H  No. of rpts: 1 premium: 5 DPMQ: 16.62 MRVSN: 14.83 brand name and manufacturer: APO-Rosuvastatin (TX) APPZUVA 10 (ZP) FRETON (AP) ROSUVASTATIN AMNEAL (EF) TERRY WHITE CHEMISTS Prepavastatin (TW)
### ROSUVASTATIN

**Restrict benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**
- The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

#### rosuvastatin 40 mg tablet, 30

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**rosuvastatin 20 mg tablet, 30**

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**rosuvastatin 5 mg tablet, 30**

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**rosuvastatin 40 mg tablet, 30**

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## ROSUVASTATIN

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

### Restricted benefit

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### rosuvastatin 20 mg tablet, 30

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### rosuvastatin 5 mg tablet, 30

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### rosuvastatin 10 mg tablet, 30

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### rosuvastatin 40 mg tablet, 30

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## ROSUVASTATIN

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

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

### Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

### Clinical criteria:
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements, **AND**
- The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

### Rosuvastatin 20 mg Tablet, 30

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- Rosuvastatin AMNEAL [EF]
- Rosuvastatin generichealth [HQ]
- Rosuvastatin RBX [RA]
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### Rosuvastatin 5 mg Tablet, 30

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### Rosuvastatin 10 mg Tablet, 30

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### Rosuvastatin 40 mg Tablet, 30

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- Rosuvastatin generichealth [HQ]
- Rosuvastatin RBX [RA]
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### Simvastatin

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

### Simvastatin 5 mg Tablet, 30

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- Simvat [AF]

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- Ransim [RA]
- Simvar 20 [RW]
- Simvastin-GA 20 [ED]
- Simvastin Sandoz [SZ]
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<td>Simvastatin generichealth</td>
<td>Simvastatin Sandoz [SZ]</td>
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## simvastatin 80 mg tablet, 30

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## simvastatin 10 mg tablet, 30

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### SIMVASTATIN

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

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

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

**Clinical criteria:**

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

• **FENOFIBRATE**
  
  Note: The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

  **Restricted benefit**
  For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

### fenofibrate 48 mg tablet, 60

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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>Lipidil [GO]</td>
<td>30.60</td>
<td>31.81</td>
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### fenofibrate 145 mg tablet, 30

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Lipidil [GO]</td>
<td>40.38</td>
<td>38.80</td>
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</table>

• **FENOFIBRATE**
  
  Note: The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

  **Restricted benefit**
  For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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

### fenofibrate 48 mg tablet, 60

<table>
<thead>
<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
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<td>31.81</td>
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### fenofibrate 145 mg tablet, 30

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<td>Lipidil [GO]</td>
<td>40.38</td>
<td>38.80</td>
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GEMFIBROZIL

Note: The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

Gemfibrozil 600 mg tablet, 60

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Bile acid sequestrants

CHOLESTYRAMINE

Cholestyramine 4 g powder for oral liquid, 50 sachets

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Other lipid modifying agents

EVOLOCUMAB

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

Authority required
Familial homozygous hypercholesterolaemia
Treatment Phase: Initial treatment
Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, AND
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment; OR
• Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre and must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Treatment criteria:**
• Must be treated by a consultant physician or in consultation with a consultant physician.

A clinically important product-related adverse event is defined as follows:
(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporarily associated with statin treatment; or
(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

The authority application must be made in writing and must include:
- A completed authority prescription form;
- A completed Familial homozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and
- The date of consultation and the full name of the consultant physician; and
- A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Familial homozygous hypercholesterolaemia
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Familial homozygous hypercholesterolaemia
Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment; OR
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre and must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

**Treatment criteria:**
**CARDIOVASCULAR SYSTEM**

- Must be treated by a consultant physician or in consultation with a consultant physician. A clinically important product-related adverse event is defined as follows:
  1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
  2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
  3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

The authority application must be made in writing and must include:

- A completed authority prescription form; and
- A completed Familial homozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and
- The date of consultation and the full name of the consultant physician; and
- A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Familial homozygous hypercholesterolaemia

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Familial homozygous hypercholesterolaemia

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; **OR**
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre after at least 3 months of treatment at a maximum tolerated dose of an HMG CoA reductase inhibitor (statin), in conjunction with dietary therapy and exercise, prior to initiation of treatment with this drug; **OR**
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre after having developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of statin treatment, prior to initiation of treatment with this drug; **OR**
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre prior to initiation of treatment with this drug, and must be contraindicated to treatment with an HMG CoA reductase inhibitor (statin).

**Treatment criteria:**

- Must be treated by a consultant physician or in consultation with a consultant physician. The date of the consultation with a consultant physician must be no more than 6 months prior to the application for a PBS authority. The full name of the consultant physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level prior to initiation of treatment with this drug must be provided at the time of application. With the exception of patients contraindicated to a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

A clinically important product-related adverse event is defined as follows:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
Ezetimibe

Note Continuing Therapy Only:

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Ezetimibe 140 mg/mL injection, 1 mL injection device

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### EZETIMIBE

**Note** Continuing Therapy Only:

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

**Authority required (STREAMLINED)**

5537

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

5543

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. Where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise.

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise.

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**5538**

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypercholesterolaemia that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

**5544**

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia. **AND**
- Patient must have symptomatic cerebrovascular disease.

**5594**

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease. **AND**
Inadequate control with a statin is defined as follows:

1. The patient has a family history of coronary heart disease.
2. The patient has hypertension.

A clinically important product-related adverse event is defined as follows:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with treatment with a statin.
2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes.
3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.
**CARDIOVASCULAR SYSTEM**

**Authority required (STREAMLINED)**

5577

Hypercholesterolaemia

**Clinical criteria:**

- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin).

**ezetimibe 10 mg tablet, 30**

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**LIPID MODIFYING AGENTS, COMBINATIONS**

**HMG CoA reductase inhibitors in combination with other lipid modifying agents**

- **EZETIMIBE + ATORVASTATIN**

  **Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

4068

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise.

**Authority required (STREAMLINED)**

4085

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise.

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise.

**Authority required (STREAMLINED)**

4086

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

*4121*

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

*4097*

Hypercholesterolaemia

**Clinical criteria:**
- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

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**EZETIMIBE + ATORVASTATIN**

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

**Authority required (STREAMLINED)**

*4068*

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4089
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)
threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4120

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated.

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4121

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated.

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4097

**Hypercholesterolaemia**

**Clinical criteria:**
- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

### 4353

**Hypercholesterolaemia**

**Clinical criteria:**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

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**EZETIMIBE + SIMVASTATIN**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

4068

**Hypercholesterolaemia**

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4085

**Hypercholesterolaemia**

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have diabetes mellitus, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4086

**Hypercholesterolaemia**

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4069

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4096

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4120

**Hypercholesterolaemia**

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4121

**Hypercholesterolaemia**
Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
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**Authority required (STREAMLINED)**

**4097**
Hypercholesterolaemia
Clinical criteria:
- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

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**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

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**EZETIMIBE + SIMVASTATIN**

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

**Authority required (STREAMLINED)**

**4068**
Hypercholesterolaemia
Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**
Hypercholesterolaemia
Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that...
threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4086

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterolevels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated.

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4089

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterolevels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:
1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
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Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:
1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
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Hypercholesterolaemia

Clinical criteria:
- Patient must have homozygous familial hypercholesterolaemia, AND
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Hypercholesterolaemia

Clinical criteria:
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), AND
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:
(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

ezetimibe 10 mg + simvastatin 20 mg tablet, 30
ROSUVASTATIN (&) EZETIMIBE

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

Authority required (STREAMLINED)
4068
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)
4085
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)
4086
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be
Inadequate control with a statin is defined as follows:

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**Authority required (STREAMLINED)**

**4096**
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4121**
Hypercholesterolaemia

Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have hypertension.
Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4097**
Hypercholesterolaemia

**Clinical criteria:**
- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

| Rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty/Packs: 100207F         | No. of Rpts: 5  | Premium$: 71.83 | DPMQ$: 38.80    | MRVSN$: 38.80   | Brand Name and Manufacturer: Rosuzet Composite Pack [MK] |
| Max.Qty/Packs: 100208G         | No. of Rpts: 5  | Premium$: 69.32 | DPMQ$: 38.80    | MRVSN$: 38.80   | Brand Name and Manufacturer: Rosuzet Composite Pack [MK] |
| Max.Qty/Packs: 100201X         | No. of Rpts: 5  | Premium$: 70.33 | DPMQ$: 38.80    | MRVSN$: 38.80   | Brand Name and Manufacturer: Rosuzet Composite Pack [MK] |

**ROSUVASTIN (&) EZETIMIBE**

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

**Authority required (STREAMLINED)**

**4068**
Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**
Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required** (STREAMLINED)

4086

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required** (STREAMLINED)

4089

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
- Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

Hypercholesterolaemia

**Clinical criteria:**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

Hypercholesterolaemia

**Clinical criteria:**
- Patient must have homozygous familial hypercholesterolaemia, **AND**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

Hypercholesterolaemia

**Clinical criteria:**
- Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Rosuzet**

**Rosuzet Composite Pack [MK]**

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**HMG CoA reductase inhibitors, other combinations**
### AMLODIPINE + ATORVASTATIN

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

**Angina**

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be one in whom blood pressure is inadequately controlled with other classes of antihypertensive agents, **AND**
- The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

**Restricted benefit**

**Angina**

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must have angina which is inadequately controlled with other classes of anti-anginal agents, **AND**
- The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be intolerant of the side effects of other classes of antihypertensive agents, **AND**
- Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

**Restricted benefit**

**Angina**

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
- Patient must be intolerant of the side effects of other classes of anti-anginal agents, **AND**
- Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

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### General

**DERMATOLOGICALS**

**ANTIFUNGALS FOR DERMATOLOGICAL USE**

**ANTIFUNGALS FOR TOPICAL USE**

#### Antibiotics

- **NYSTATIN**

  Authority required (STREAMLINED) 6434

  Fungal or yeast infection

  **Population criteria:**
  - Patient must be an Aboriginal or a Torres Strait Islander person.

- **nystatin 100 000 units/g cream, 15 g**

  **Brand Name and Manufacturer:**
  - *Mycostatin [FM]*

  **DPMQ**
  - 21.11

  **MRVSN**
  - 22.32

  **Manufacturer:**
  - *Mycostatin [FM]*

#### Imidazole and triazole derivatives

- **KETOCONAZOLE**

  Authority required (STREAMLINED) 6434

  Fungal or yeast infection

  **Population criteria:**
  - Patient must be an Aboriginal or a Torres Strait Islander person.

- **ketoconazole 2% shampoo, 60 mL**

  **Brand Name and Manufacturer:**
  - *Nizoral 2% [JT]*

  **DPMQ**
  - 21.58

  **MRVSN**
  - 22.79

  **Manufacturer:**
  - *Nizoral 2% [JT]*

- **ketoconazole 2% cream, 30 g**

  **Brand Name and Manufacturer:**
  - *Nizoral 2% Cream [JT]*

  **DPMQ**
  - 25.63

  **MRVSN**
  - 26.84

  **Manufacturer:**
  - *Nizoral 2% Cream [JT]*

- **ketoconazole 1% shampoo, 100 mL**

  **Brand Name and Manufacturer:**
  - *Nizoral 1% [JT]*

  **DPMQ**
  - 20.95

  **MRVSN**
  - 22.16

  **Manufacturer:**
  - *Nizoral 1% [JT]*

#### MICONAZOLE

Authority required (STREAMLINED)
Fungal or yeast infection

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

### miconazole nitrate 2% cream, 30 g

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### miconazole nitrate 2% dusting powder, 30 g

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### miconazole 2% solution, 30 mL

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>19.32</td>
<td>20.53</td>
<td>21.77</td>
<td>Daktarin Tincture [JT]</td>
</tr>
</tbody>
</table>

### miconazole nitrate 2% cream, 70 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>19.80</td>
<td>21.14</td>
<td>22.02</td>
<td>Daktarin [JT]</td>
</tr>
</tbody>
</table>

### Other antifungals for topical use

- **TERBINAFINE**
  
  **Authority required (STREAMLINED)**

  6434
  
  Fungal or yeast infection
  
  **Population criteria:**
  - Patient must be an Aboriginal or a Torres Strait Islander person.

  Authority required (STREAMLINED)

  6412
  
  Fungal or yeast infection
  
  **Clinical criteria:**
  - The condition must be fungal; OR
  - The condition must be due to yeast.

  **Population criteria:**
  - Patient must be 18 years of age or less.

### TERBINAFINE

**Authority required (STREAMLINED)**

6434

Fungal or yeast infection

**Population criteria:**
- Patient must have failed to respond to topical treatment, AND
- Patient must have failed to respond to griseofulvin.

### GRISEOFULVIN

- **GRISEOFULVIN**

  griseofulvin 125 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>27.15</td>
<td>28.36</td>
<td>29.57</td>
<td>Grisovin 500 [QA]</td>
</tr>
</tbody>
</table>

  griseofulvin 500 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>28.09</td>
<td>29.30</td>
<td>30.55</td>
<td>Grisovin 500 [QA]</td>
</tr>
</tbody>
</table>
**DERMATOLOGICALS**

**Population criteria:**
- Patient must be 18 years of age or less.

**terbinafine 250 mg tablet, 42**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>30.00</td>
<td>31.21</td>
<td>..</td>
</tr>
</tbody>
</table>

- GenRx Terbinafine [GX]
- Sebifin 250 [RA]
- Terbinafine AN [EA]
- Terbinafine GH [GQ]
- Tinasil [AF]
- Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
- Tamsil [RW]
- Terbinafine-DRLA [RZ]
- Terbinafine Sandoz [SZ]

**TERBINAFINE**

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

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

**Authority required**

**Onychomycosis**

**Clinical criteria:**
- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider, **OR**
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old.

**terbinafine 250 mg tablet, 42**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>30.00</td>
<td>31.21</td>
<td>..</td>
</tr>
</tbody>
</table>

- GenRx Terbinafine [GX]
- Sebifin 250 [RA]
- Terbinafine AN [EA]
- Terbinafine GH [GQ]
- Tinasil [AF]
- Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
- Tamsil [RW]
- Terbinafine-DRLA [RZ]
- Terbinafine Sandoz [SZ]

**ANTIPSORIATICS**

**ANTIPSORIATICS FOR TOPICAL USE**

**Tars**

**PREPARED COAL TAR**

**prepared coal tar 1% w/w lotion, 100 mL**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>33.11</td>
<td>34.32</td>
<td>..</td>
</tr>
</tbody>
</table>

- Exorex [GN]

**coal tar prepared 2% foam, 100 g**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>34.27</td>
<td>35.48</td>
<td>..</td>
</tr>
</tbody>
</table>

- Scytera [RZ]

**Other antipsoriatics for topical use**

**CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**6873**

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy, **AND**
- Patient must require more than 30 grams of product per month.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>63.11</td>
<td>38.80</td>
<td>..</td>
</tr>
</tbody>
</table>

- Daivobet 50/500 gel [LO]
CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

Restricted benefit
Chronic stable plaque type psoriasis vulgaris

Clinical criteria:
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td></td>
<td>37.10</td>
<td>38.31</td>
<td></td>
<td>* Calcipotriol/Betamethasone Sandoz 50/500 [SZ] * Daivobet [LO]</td>
</tr>
</tbody>
</table>

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td></td>
<td>37.10</td>
<td>38.31</td>
<td></td>
<td>Daivobet 50/500 gel [LO]</td>
</tr>
</tbody>
</table>

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td></td>
<td>83.33</td>
<td>38.80</td>
<td></td>
<td>Enstilar [LO]</td>
</tr>
</tbody>
</table>

ANTIPSORIATICS FOR SYSTEMIC USE
Retinoids for treatment of psoriasis

ACITRETIN

Caution This drug is a potent teratogen - pregnancy should be avoided for at least two years after cessation of therapy.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)
5789
Severe intractable psoriasis

Authority required (STREAMLINED)
5727
Severe disorders of keratinisation

Acitretin 25 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td></td>
<td>207.38</td>
<td>38.80</td>
<td>* Neotigason [UA] * Novatin [TX]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* ZETIN [RW]</td>
<td></td>
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</tbody>
</table>

Acitretin 10 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td></td>
<td>107.34</td>
<td>38.80</td>
<td>* Neotigason [UA] * Novatin [TX]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* ZETIN [RW]</td>
<td></td>
</tr>
</tbody>
</table>

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

SILVER SULFADIAZINE

Restricted benefit
Infection
Treatment Phase: Prevention and treatment

Clinical criteria:
- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

Restricted benefit
Stasis ulcers

Silver sulfadiazine 1% cream, 50 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>21.62</td>
<td>22.83</td>
<td></td>
<td>Flamazine [SN]</td>
</tr>
</tbody>
</table>
### HYDROCORTISONE ACETATE

**Restricted benefit**
Corticosteroid-responsive dermatoses

**HYDROCORTISONE ACETATE**

<table>
<thead>
<tr>
<th>Hydrocortisone acetate 1% cream, 50 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2881P</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hydrocortisone acetate 1% ointment, 50 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2882Q</td>
</tr>
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### HYDROCORTISONE ACETATE

**Restricted benefit**
Corticosteroid-responsive dermatoses

**HYDROCORTISONE ACETATE**

<table>
<thead>
<tr>
<th>Hydrocortisone acetate 1% cream, 50 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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</table>

<table>
<thead>
<tr>
<th>Hydrocortisone acetate 1% ointment, 50 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>5114E</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

### TRIAMCINOLONE

**Restricted benefit**
Corticosteroid-responsive dermatoses

**Triamcinolone acetonide 0.02% cream, 100 g**

| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ |
| 2117K        | 2           | *18.03    | 19.24  |       |
|              |             | *3.28     | 21.31  | 19.24  |

**Triamcinolone acetonide 0.02% ointment, 100 g**

| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ |
| 2118L        | 2           | *18.03    | 19.24  |       |
|              |             | *3.28     | 21.31  | 19.24  |

### BETAMETHASONE DIPROPIONATE

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

**Restricted benefit**
Corticosteroid-responsive dermatoses

**BETAMETHASONE DIPROPIONATE**

<table>
<thead>
<tr>
<th>Betamethasone (as dipropionate) 0.05% cream, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1115Q</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Betamethasone (as dipropionate) 0.05% ointment, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1119X</td>
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<tr>
<td></td>
</tr>
</tbody>
</table>
### BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**Corticosteroid-responsive dermatoses**

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

<table>
<thead>
<tr>
<th>betamethasone (as dipropionate) 0.05% cream, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty</td>
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<tr>
<td>--------</td>
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<table>
<thead>
<tr>
<th>betamethasone (as dipropionate) 0.05% ointment, 15 g</th>
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</thead>
<tbody>
<tr>
<td>Max Qty</td>
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<tr>
<td>--------</td>
</tr>
<tr>
<td>10795E</td>
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</tbody>
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### BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**Corticosteroid-responsive dermatoses**

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

<table>
<thead>
<tr>
<th>betamethasone (as dipropionate) 0.05% cream, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty</td>
</tr>
<tr>
<td>--------</td>
</tr>
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<table>
<thead>
<tr>
<th>betamethasone (as dipropionate) 0.05% ointment, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty</td>
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<tr>
<td>--------</td>
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### BETAMETHASONE DIPROPIONATE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

**Corticosteroid-responsive dermatoses**

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

<table>
<thead>
<tr>
<th>betamethasone (as dipropionate) 0.05% cream, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty</td>
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<tr>
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</tr>
<tr>
<td>10813D</td>
</tr>
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<table>
<thead>
<tr>
<th>betamethasone (as dipropionate) 0.05% ointment, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>10821M</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
**Corticosteroid-responsive dermatoses**

**Clinical criteria:**
- The condition must cover 60-80% of the patient's body surface area.

### betamethasone (as dipropionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eleuphrat [FR]</td>
<td>8</td>
<td>5</td>
<td>*57.79</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>Diprosone [MK]</td>
<td>8</td>
<td>5</td>
<td>*19.60</td>
<td>38.80</td>
<td></td>
</tr>
</tbody>
</table>

### betamethasone (as dipropionate) 0.05% ointment, 15 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
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<td>5</td>
<td>*57.79</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>Diprosone [MK]</td>
<td>8</td>
<td>5</td>
<td>*19.60</td>
<td>38.80</td>
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</tr>
</tbody>
</table>

**BETAMETHASONE DIPROPIONATE**

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### betamethasone (as dipropionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eleuphrat [FR]</td>
<td>10</td>
<td>5</td>
<td>*69.45</td>
<td>38.80</td>
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</tr>
<tr>
<td>Diprosone [MK]</td>
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<td>5</td>
<td>*24.50</td>
<td>38.80</td>
<td></td>
</tr>
</tbody>
</table>

### betamethasone (as dipropionate) 0.05% ointment, 15 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
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<tbody>
<tr>
<td>Eleuphrat [FR]</td>
<td>10</td>
<td>5</td>
<td>*69.45</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>Diprosone [MK]</td>
<td>10</td>
<td>5</td>
<td>*24.50</td>
<td>38.80</td>
<td></td>
</tr>
</tbody>
</table>

**BETAMETHASONE VALERATE**

**Restricted benefit**
Corticosteroid-responsive dermatoses

### betamethasone (as valerate) 0.02% cream, 100 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Antroquoril [FR]</td>
<td>2</td>
<td>..</td>
<td>*26.57</td>
<td>27.78</td>
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</tr>
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<tr>
<td>Celestone-M [MK]</td>
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<td>5.98</td>
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<td>Betnovate 1/5 [QA]</td>
<td>5</td>
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<td>5.98</td>
<td>32.55</td>
<td></td>
</tr>
</tbody>
</table>

**BETAMETHASONE VALERATE**

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

**Restricted benefit**
Corticosteroid-responsive dermatoses

### betamethasone (as valerate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>1</td>
<td>12.82</td>
<td>14.03</td>
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</tr>
<tr>
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<td>1</td>
<td>1</td>
<td>2.56</td>
<td>15.38</td>
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</tr>
</tbody>
</table>
**Clinical criteria:**
- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td><strong>14.55</strong></td>
<td>15.76</td>
<td></td>
<td>* Cortival 1/2 [FM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>5.12</strong></td>
<td>19.67</td>
<td>15.76</td>
<td>* Betnovate 1/2 [QA]</td>
</tr>
</tbody>
</table>

**BETAMETHASONE VALERATE**

**Note Continuing Therapy Only:**
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**Authority required (STREAMLINED)**

6246  
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 20-40% of the patient's body surface area.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td><strong>18.03</strong></td>
<td>19.24</td>
<td></td>
<td>* Cortival 1/2 [FM]</td>
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<td><strong>10.24</strong></td>
<td>28.27</td>
<td>19.24</td>
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</table>

**BETAMETHASONE VALERATE**

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

**Authority required (STREAMLINED)**

6218  
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient's body surface area.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>5</td>
<td><strong>21.49</strong></td>
<td>22.70</td>
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<td>* Cortival 1/2 [FM]</td>
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<tr>
<td></td>
<td></td>
<td><strong>15.36</strong></td>
<td>36.85</td>
<td>22.70</td>
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</tbody>
</table>

**BETAMETHASONE VALERATE**

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

**Authority required (STREAMLINED)**

6263  
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 60-80% of the patient's body surface area.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8</td>
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<tr>
<td></td>
<td></td>
<td><strong>20.48</strong></td>
<td>45.39</td>
<td>26.12</td>
<td>* Betnovate 1/2 [QA]</td>
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**BETAMETHASONE VALERATE**

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

**Authority required (STREAMLINED)**

6221  
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover >80% of the patient's body surface area.
### METHYPREDNISOLONE

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

#### Restricted benefit
Corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Pack Size</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>methylprednisolone aceponate 0.1% ointment, 15 g</td>
<td>8055Y</td>
<td>1</td>
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<td>..</td>
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<td>18.87</td>
<td>Advantan [BN]</td>
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</tr>
<tr>
<td>methylprednisolone aceponate 0.1% cream, 15 g</td>
<td>8054X</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>17.66</td>
<td>18.87</td>
<td>Advantan [BN]</td>
<td></td>
</tr>
<tr>
<td>methylprednisolone aceponate 0.1% ointment: fatty, 15 g</td>
<td>8128T</td>
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<td>..</td>
<td>17.66</td>
<td>18.87</td>
<td>Advantan [BN]</td>
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</table>

### METHYPREDNISOLONE

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

#### Authority required (STREAMLINED)
6232
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 10-20% of the patient’s body surface area.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Pack Size</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>methylprednisolone aceponate 0.1% lotion, 20 g</td>
<td>8618N</td>
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<td>19.46</td>
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</tr>
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<td>methylprednisolone aceponate 0.1% ointment, 15 g</td>
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<td>5</td>
<td>..</td>
<td>*24.23</td>
<td>25.44</td>
<td>Advantan [BN]</td>
<td></td>
</tr>
<tr>
<td>methylprednisolone aceponate 0.1% cream, 15 g</td>
<td>10842P</td>
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<td>5</td>
<td>..</td>
<td>*24.23</td>
<td>25.44</td>
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<td></td>
</tr>
<tr>
<td>methylprednisolone aceponate 0.1% ointment: fatty, 15 g</td>
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<td>5</td>
<td>..</td>
<td>*24.23</td>
<td>25.44</td>
<td>Advantan [BN]</td>
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**METHYLPREDNISOLONE**

Note Continuing Therapy Only:

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

**Authority required (STREAMLINED)**

6246

Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 20-40% of the patient’s body surface area.

**methylprednisolone aceponate 0.1% lotion, 20 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**methylprednisolone aceponate 0.1% ointment, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<td>38.60</td>
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</table>

**methylprednisolone aceponate 0.1% cream, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<tbody>
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<td>38.60</td>
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</table>

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
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<td>38.60</td>
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</table>

**METHYLPREDNISOLONE**

Note Continuing Therapy Only:

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**Authority required (STREAMLINED)**

6231

Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover >80% of the patient’s body surface area.

**methylprednisolone aceponate 0.1% lotion, 20 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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**methylprednisolone aceponate 0.1% ointment, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10845T</td>
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<td>5</td>
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<td>*76.75</td>
<td>38.80</td>
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</tbody>
</table>

**methylprednisolone aceponate 0.1% cream, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10833E</td>
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</table>

**methylprednisolone aceponate 0.1% ointment: fatty, 15 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>10843Q</td>
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**METHYLPREDNISOLONE**

Note Continuing Therapy Only:

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**Authority required (STREAMLINED)**

6218

Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient’s body surface area.
**DERMATOLOGICALS**

methylprednisolone aceponate 0.1% ointment, 15 g

<table>
<thead>
<tr>
<th>Sched</th>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10853F</td>
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methylprednisolone aceponate 0.1% cream, 15 g

<table>
<thead>
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<th>Sched</th>
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methylprednisolone aceponate 0.1% ointment: fatty, 15 g

<table>
<thead>
<tr>
<th>Sched</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
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<tr>
<td>10844R</td>
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</table>

### METHYLPREDNISOLONE

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**Authority required (STREAMLINED)**

6263 Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

methylprednisolone aceponate 0.1% ointment, 15 g

<table>
<thead>
<tr>
<th>Sched</th>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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methylprednisolone aceponate 0.1% cream, 15 g

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tr>
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methylprednisolone aceponate 0.1% ointment: fatty, 15 g

<table>
<thead>
<tr>
<th>Sched</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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### METHYLPREDNISOLONE

**Note Continuing Therapy Only:**

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

**Authority required (STREAMLINED)**

6263 Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

methylprednisolone aceponate 0.1% lotion, 20 g

<table>
<thead>
<tr>
<th>Sched</th>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10852E</td>
<td>4 5</td>
<td>*39.75 38.80 Advantan [BN]</td>
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</tbody>
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### MOMETASONE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

Corticosteroid-responsive dermatoses

mometasone furoate 0.1% cream, 15 g

<table>
<thead>
<tr>
<th>Sched</th>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
### MOMETASONE

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

#### Authority required (STREAMLINED)

6222
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 10-20% of the patient’s body surface area.

### MOMETASONE

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

#### Authority required (STREAMLINED)

6246
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 20-40% of the patient’s body surface area.
### MOMETASONE

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

**Authority required (STREAMLINED)**

#### 6218
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient's body surface area.

#### Mometasone furoate 0.1% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td></td>
<td></td>
<td>21.18</td>
<td>52.15</td>
<td>32.18</td>
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</tbody>
</table>

#### Mometasone furoate 0.1% ointment, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>32.18</td>
<td>* Momasone [QA] * Novasone [AF] * Zatamil [EO]</td>
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<td></td>
<td></td>
<td>21.18</td>
<td>52.15</td>
<td>32.18</td>
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</tbody>
</table>

### MOMETASONE

**Note Continuing Therapy Only:**
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**Authority required (STREAMLINED)**

#### 6263
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 60-80% of the patient's body surface area.

#### Mometasone furoate 0.1% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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#### Mometasone furoate 0.1% ointment, 15 g

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### MOMETASONE

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

**Authority required (STREAMLINED)**

#### 6231
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover >80% of the patient's body surface area.

#### Mometasone furoate 0.1% cream, 15 g

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#### Mometasone furoate 0.1% lotion, 30 mL

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mometasone furoate 0.1% ointment, 15 g

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**MOMETASONE**

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**Corticosteroid-responsive dermatoses**

Authority required (STREAMLINED)

6263
Corticosteroid-responsive dermatoses
Clinical criteria:
- The condition must cover 60-80% of the patient's body surface area.

Authority required (STREAMLINED)

6218
Corticosteroid-responsive dermatoses
Clinical criteria:
- The condition must cover 40-60% of the patient's body surface area.

mometasone furoate 0.1% lotion, 30 mL

<table>
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**CLOBETASOL**

Authority required (STREAMLINED)

5461
Moderate to severe scalp psoriasis
Clinical criteria:
- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.
Population criteria:
- Patient must be aged 18 years or older.

clobetasol propionate 0.05% shampoo, 125 mL

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**ANTI-ACNE PREPARATIONS**

**ANTI-ACNE PREPARATIONS FOR TOPICAL USE**

**Retinoids for topical use in acne**

**ADAPALENE + BENZOYL PEROXIDE**

Restricted benefit
Severe acne vulgaris
Treatment Phase: Acute treatment
Clinical criteria:
- The treatment must in combination with an oral antibiotic.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

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**ADAPALENE + BENZOYL PEROXIDE**

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

Restricted benefit
Severe acne vulgaris
**DERMATOLOGICALS**

**ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE**

**Retinoids for treatment of acne**

### ISOTRETINOIN

**Caution** This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**

5224

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

**isotretinoin 40 mg capsule, 30**

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**isotretinoin 10 mg capsule, 60**

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**isotretinoin 20 mg capsule, 60**

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### OTHER DERMATOLOGICAL PREPARATIONS

**OTHER DERMATOLOGICAL PREPARATIONS**

**Agents for dermatitis, excluding corticosteroids**

### PIMECROLIMUS

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

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

**Authority required (STREAMLINED)**

5482

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority required (STREAMLINED)**

5472

Atopic dermatitis

**Treatment Phase:** Short-term (up to 3 weeks) intermittent treatment

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
The condition must have been initially diagnosed more than three months prior to this treatment, AND
Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.
Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate
and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2
consecutive occasions; or
(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost
immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2
consecutive occasions

pimecrolimus 1% cream, 15 g

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**Other dermatologicals**

**DAPSONE**

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

dapsone 25 mg tablet, 100

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**IMIQUIMOD**

- Note The patient or carer must be able to understand and administer the imiquimod dosing regimen.
- Note No increase in the maximum quantity or number of units may be authorised.
- Note No increase in the maximum number of repeats may be authorised.
- Note Treatment of recurrent (previously treated) lesions will not be authorised.
- Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form
  imiquimod multi-use pump are equivalent for the purposes of substitution.

**Authority required**

Superficial basal cell carcinoma

Clinical criteria:
- The condition must be previously untreated, AND
- The condition must be confirmed by biopsy, AND
- Patient must have normal immune function, AND
- The condition must not be suitable for treatment with surgical excision; OR
- The condition must not be suitable for treatment with cryotherapy; OR
- The condition must not be suitable for treatment with curettage with diathermy, AND
- Patient must require topical drug therapy.
The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

imiquimod 5% cream, 2 x 2 g

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imiquimod 5% cream, 12 x 250 mg sachets

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**GENITO URINARY SYSTEM AND SEX HORMONES**

**OTHER GYNECOLOGICALS**

**CONTRACEPTIVES FOR TOPICAL USE**

*Intrauterine contraceptives*
LEVONORGESTREL

Restricted benefit

Contraception

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:
- The treatment must be in a patient where oral treatments are ineffective.

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:
- The treatment must be in a patient where oral treatments are contraindicated.

levonorgestrel 52 mg intrauterine drug delivery system, 1 system

<table>
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OTHER GYNECOLOGICALS

Prolactine inhibitors

BROMOCRIPTINE

Restricted benefit

Prevention of the onset of lactation

Clinical criteria:
- The treatment must occur in the puerperium, AND
- The treatment must be for medical reasons.

bromocriptine 2.5 mg tablet, 30

<table>
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BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Restricted benefit

Parkinson disease

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:
- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:
- Patient must have had surgery for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

<table>
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<tr>
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CABERGOLINE

Restricted benefit

Prevention of the onset of lactation

Clinical criteria:
- The treatment must occur in the puerperium, AND
- The treatment must be for medical reasons.
### CABERGOLINE

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must be one in whom surgery is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must have had radiotherapy for this condition with incomplete resolution.

### QUINAGOLIDE

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must be one in whom surgery is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia

- **Clinical criteria:**
  - Patient must have had radiotherapy for this condition with incomplete resolution.

### SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

#### HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

**Progestogens and estrogens, fixed combinations**

#### LEVONORGESTREL + ETHINYLESTRODIOL

**levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

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<td>Drug Description</td>
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<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
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<tr>
<td>ethinylestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
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<td>..</td>
<td>17.20</td>
<td>18.41</td>
</tr>
<tr>
<td>levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&amp;) inert substance tablet [7], 4 x 28</td>
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<td>1 2</td>
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<td>17.20</td>
<td>18.41</td>
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<tr>
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<td>norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&amp;) inert substance tablet [7], 4 x 28</td>
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<td>Progestogens and Estrogens, Sequential Preparations</td>
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<td>Progestogens</td>
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<td>levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]</td>
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<td>MEDROXYPROGESTERONE</td>
<td>medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial</td>
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NORETHISTERONE

norethisterone 350 microgram tablet, 4 x 28

<table>
<thead>
<tr>
<th>1967M</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Noriday 28 Day [PF]</td>
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</tbody>
</table>

ANDROGENS

3-oxoandrostenedione (4) derivatives

TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:
• Patient must have an established pituitary or testicular disorder.

Treatment criteria:
• Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:
• Patient must not have an established pituitary or testicular disorder, AND
• The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:
• Patient must be aged 40 years or older.

Treatment criteria:
• Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:
(i) testosterone level of less than 6 nmol per litre; OR
(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:
• Patient must be under 18 years of age.

Treatment criteria:
• Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:
• Patient must be under 18 years of age.

Treatment criteria:
• Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

constitutional delay of growth or puberty

Population criteria:
• Patient must be under 18 years of age.

Treatment criteria:
• Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.
testosterone 2.5 mg/24 hours patch, 60
8460G Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
‡1 5 .. 88.31 38.80 Androderm [GN]

testosterone 5 mg/24 hours patch, 30
8619P Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
‡1 5 .. 88.31 38.80 Androderm [GN]

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets
8830R Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
‡1 5 .. 88.31 38.80 Testogel [HB]

testosterone 5% (50 mg/mL) cream, 50 mL
10378F Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
‡1 6 .. 73.95 38.80 AndroForte 5 [LX]

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations
10380H Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
‡1 6 .. 87.70 38.80 Testogel [HB]

testosterone 2% (30 mg/actuation) solution, 60 actuations
2341F Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
‡1 5 .. 76.76 38.80 Axiron [LY]

**TESTOSTERONE ENANTHATE**

**Authority required**

**Androgen deficiency**

**Clinical criteria:**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

**Androgen deficiency**

**Clinical criteria:**
- Patient must not have an established pituitary or testicular disorder, AND
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**
- Patient must be aged 40 years or older.

**Treatment criteria:**
- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:
(i) testosterone level of less than 6 nmol per litre; OR
(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

**Micropenis**

**Population criteria:**
- Patient must be under 18 years of age.

**Pubertal induction**

**Population criteria:**
- Patient must be under 18 years of age.
Treatment criteria:
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**
- Patient must be under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>3</td>
<td>33.44</td>
<td>34.65</td>
<td></td>
<td>Primeston Depot [BN]</td>
</tr>
</tbody>
</table>

**TESTOSTERONE UNDECANOATE**

**Authority required**

Androgen deficiency

**Clinical criteria:**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Androgen deficiency

**Clinical criteria:**
- Patient must not have an established pituitary or testicular disorder, AND
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**
- Patient must be aged 40 years or older.

**Treatment criteria:**
- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:
(i) testosterone level of less than 6 nmol per litre; OR
(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority required**

Micropenis

**Population criteria:**
- Patient must be under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Pubertal induction

**Population criteria:**
- Patient must be under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority required**

Constitutional delay of growth or puberty
Population criteria:
- Patient must be under 18 years of age.

Treatment criteria:
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone undecanoate 40 mg capsule, 60

<table>
<thead>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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testosterone undecanoate 1 g/4 mL injection, 4 mL vial

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<th>MRVSN $</th>
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<tr>
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<td>132.86</td>
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<td>Reandron 1000 [BN]</td>
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ESTROGENS

Natural and semisynthetic estrogens, plain

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

  oestradiol valerate 1 mg tablet, 56

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>1</td>
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<td>15.66</td>
<td>16.87</td>
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  oestradiol 2 mg tablet, 56

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<td>18.50</td>
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  oestradiol valerate 2 mg tablet, 56

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  oestradiol 10 microgram modified release pessary, 18

<table>
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<tr>
<td>1</td>
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<td>..</td>
<td>33.16</td>
<td>34.37</td>
<td>Vagifem Low [NO]</td>
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</table>

- **OESTRADIOL**
  
  **Note** Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

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

  oestradiol 100 microgram/24 hours patch, 8

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tr>
<td>‡1</td>
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<td>22.14</td>
<td>23.35</td>
<td>Estraderm MX 100 [JU]</td>
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  oestradiol 100 microgram/24 hours patch, 8

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>22.14</td>
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  oestradiol 37.5 microgram/24 hours patch, 8

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<tbody>
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  oestradiol 75 microgram/24 hours patch, 4

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<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>22.14</td>
<td>23.35</td>
<td>Climara 75 [BN]</td>
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GENITO URINARY SYSTEM AND SEX HORMONES

**OESTRADIOL**

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

**Oestradiol 75 microgram/24 hours patch, 8**

<table>
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<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Estradot 75 [SZ]</td>
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<td>5</td>
<td>..</td>
<td>22.14</td>
<td>23.35</td>
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**Oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

<table>
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<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Sandrena [AS]</td>
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<td>21.58</td>
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**Oestradiol 50 microgram/24 hours patch, 4**

<table>
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<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Climara 50 [BN]</td>
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<td>5</td>
<td>..</td>
<td>20.37</td>
<td>21.58</td>
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**Oestradiol 25 microgram/24 hours patch, 8**

<table>
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<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
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<td>Estraderm MX 25 [JU]</td>
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<td>5</td>
<td>..</td>
<td>20.37</td>
<td>21.58</td>
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**Oestradiol 25 microgram/24 hours patch, 8**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estraderm MX 50 [JU]</td>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>20.37</td>
<td>21.58</td>
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**Oestradiol 100 microgram/24 hours patch, 4**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Climara 100 [BN]</td>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>22.14</td>
<td>23.35</td>
</tr>
</tbody>
</table>

**OESTRIOL**

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

**Oestradiol 500 microgram pessary, 15**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovestin Ovula [AS]</td>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>23.35</td>
<td>24.56</td>
</tr>
</tbody>
</table>

**Oestradiol 0.1% (1 mg/g) cream, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovestin [AS]</td>
<td>†1</td>
<td>1</td>
<td>..</td>
<td>21.56</td>
<td>22.77</td>
</tr>
</tbody>
</table>

**PROGESTOGENS**

*Pregnen (4) derivatives*

**MEDROXYPROGESTERONE**

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

**Medroxyprogesterone acetate 10 mg tablet, 30**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ralovera [FZ]</td>
<td>†6</td>
<td>2</td>
<td>6.70</td>
<td>24.66</td>
<td>19.17</td>
</tr>
<tr>
<td>Provera [PF]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Genito Urinary System and Sex Hormones

#### MEDROXYPROGESTERONE

**Restricted benefit**

**Endometriosis**

<table>
<thead>
<tr>
<th>Substance</th>
<th>5 mg tablet, 56</th>
<th>10 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>medroxyprogesterone acetate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2323G</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No of Rpts</td>
<td>Premium</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
</tr>
<tr>
<td>6.70</td>
<td>25.79</td>
<td>20.30</td>
</tr>
</tbody>
</table>

#### NORETHISTERONE

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>5 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>norethisterone</td>
<td></td>
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<tr>
<td>2993M</td>
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<tr>
<td>Max Qty Packs</td>
<td>No of Rpts</td>
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<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>6.70</td>
<td>40.69</td>
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#### PROGESTOGENS AND ESTROGENS IN COMBINATION

**Progestogens and estrogens, fixed combinations**

<table>
<thead>
<tr>
<th>Substance</th>
<th>1 mg + dydrogesterone 5 mg tablet, 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>oestradiol + dydrogesterone</td>
<td></td>
</tr>
<tr>
<td>10142T</td>
<td></td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>oestradiol + dydrogesterone</td>
<td></td>
</tr>
<tr>
<td>8427M</td>
<td></td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>oestradiol + dydrogesterone</td>
<td></td>
</tr>
<tr>
<td>8428N</td>
<td></td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

#### NORETHISTERONE + OESTRADIOL

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>50 microgram/24 hours patch ([4]) &amp; 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch ([4]), 1 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>oestradiol + norethisterone acetate</td>
<td></td>
</tr>
<tr>
<td>8426L</td>
<td></td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>
oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>¶1</td>
<td>5</td>
<td></td>
<td>22.14</td>
<td>23.35</td>
<td></td>
<td>Estalis sequi 50/140 [SZ]</td>
</tr>
</tbody>
</table>

### OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE

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

<table>
<thead>
<tr>
<th>oestradiol 1 mg tablet [14] (&amp;) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 1 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max.Qty</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>¶1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>oestradiol 2 mg tablet [14] (&amp;) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 1 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max.Qty</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>¶1</td>
</tr>
</tbody>
</table>

### GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

### FOLLITROPIN ALFA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

<table>
<thead>
<tr>
<th>follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max.Qty</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max.Qty</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<p>| follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge |
|--------------------------------------------------------------------------------|---|---|---|---|---|---|</p>
<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td></td>
<td>*369.22</td>
<td>38.80</td>
<td></td>
<td>Gonal-f Pen [SG]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max.Qty</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<p>| follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge |
|--------------------------------------------------------------------------------|---|---|---|---|---|---|</p>
<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td></td>
<td>*551.44</td>
<td>38.80</td>
<td></td>
<td>Gonal-f Pen [SG]</td>
</tr>
</tbody>
</table>

<p>| follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices |
|--------------------------------------------------------------------------------|---|---|---|---|---|---|</p>
<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td></td>
<td>*915.85</td>
<td>38.80</td>
<td></td>
<td>Bemfola [FX]</td>
</tr>
</tbody>
</table>
FOLLITROPIN BETA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Reserved benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Reserved benefit

Infertility

Clinical criteria:
- The condition must be due to hypogonadotrophic hypogonadism, AND
- The treatment must be following failure of 6 months’ treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, AND
- The treatment must be administered with human chorionic gonadotrophin.

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>.</td>
<td>*924.87</td>
<td>38.80</td>
<td>Puregon 900 IU/1.08 mL [MK]</td>
</tr>
</tbody>
</table>

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>.</td>
<td>*480.55</td>
<td>38.80</td>
<td>Puregon 300 IU/0.36 mL [MK]</td>
</tr>
</tbody>
</table>

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>.</td>
<td>623.69</td>
<td>38.80</td>
<td>Puregon 600 IU/0.72 mL [MK]</td>
</tr>
</tbody>
</table>

HUMAN CHORIONIC GONADOTROPIN

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Reserved benefit

Anovulatory infertility

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Reserved benefit

Infertility

Population criteria:
- Patient must be male.

Clinical criteria:
- The condition must be due to hypogonadotrophic hypogonadism.

Reserved benefit

Infertility

Population criteria:
- Patient must be male.

Clinical criteria:
- The condition must be associated with isolated luteinising hormone deficiency.

Reserved benefit

Combined deficiency of human growth hormone and gonadotrophins

Population criteria:
- Patient must be male.

Clinical criteria:
- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

Reserved benefit

Hypogonadism or delayed puberty

Population criteria:
- Patient must be male, AND
- Patient must be aged 16 years or older.

Clinical criteria:
- Patient must show clinical evidence of the condition, AND
• The treatment must not extend beyond 6 months.

human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11148R</td>
<td>1</td>
<td>..</td>
<td>45.04</td>
<td>38.80</td>
<td>Pregnyl [MK]</td>
</tr>
</tbody>
</table>

**Ovulation stimulants, synthetic**

**CLOMIFENE**

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Restricted benefit
- Anovulatory infertility
- Restricted benefit
- Patients undergoing in-vitro fertilisation

clomifene citrate 50 mg tablet, 10

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1211R</td>
<td>1</td>
<td>..</td>
<td>35.52</td>
<td>36.73</td>
<td>Clomid [SW]</td>
</tr>
</tbody>
</table>

**ANTIANDROGENS**

Antiandrogens, plain

**CYPROTERONE**

cyproterone acetate 50 mg tablet, 50

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1270W</td>
<td>2</td>
<td>..</td>
<td>*82.69</td>
<td>38.80</td>
<td>ANTERONE 50 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cypro [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cyproterone AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cypro [ER]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Cypro 50 [QA]</td>
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<td></td>
<td></td>
<td></td>
<td>Cyprostat [SY]</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Cyproterone Sandoz [HX]</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>GenRx Cyproterone Acetate [GX]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8019C</td>
<td>1</td>
<td>..</td>
<td>66.87</td>
<td>38.80</td>
<td>ANTERONE 100 [RW]</td>
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<td></td>
<td>Cypro 100 [AF]</td>
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<td>Cyproterone AN [EA]</td>
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<td>GenRx Cyproterone Acetate [GX]</td>
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<td>Cypro 100 [QA]</td>
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<td>Cyprostat-100 [SY]</td>
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<td>Cyproterone Sandoz [HX]</td>
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<td></td>
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<td></td>
<td>Procur 100 [ED]</td>
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</tbody>
</table>

**CYPROTERONE**

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

5532
Moderate to severe androgenisation

Clinical criteria:
- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

Population criteria:
- Patient must be female.

Clinical criteria:
- Patient must not be pregnant.

cyproterone acetate 100 mg tablet, 50

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8019C</td>
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<td>..</td>
<td>66.87</td>
<td>38.80</td>
<td>Androcur-100 [BN]</td>
</tr>
</tbody>
</table>

**CYPROTERONE**

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

5532
Moderate to severe androgenisation

Clinical criteria:
- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

Population criteria:
- Patient must be female.

Clinical criteria:
- Patient must not be pregnant.

cyproterone acetate 50 mg tablet, 20

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium ($)</th>
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<th>MRVSN ($)</th>
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<td>25.41</td>
<td>26.62</td>
<td>ANTERONE 50 [RW]</td>
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<td></td>
<td>Cypro [AF]</td>
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<td>Cyproterone AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>Cypro 50 [QA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Cyprostat [SY]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Cyproterone Sandoz [HX]</td>
</tr>
</tbody>
</table>

**OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM**

Antigonadotropins and similar agents

**DANAZOL**

Caution Pregnancy must be excluded prior to administration of this drug.

Authority required (STREAMLINED)

6293
Endometriosis
Clinical criteria:
- The condition must be visually proven.
 Authority required (STREAMLINED)
6285
Hereditary angio-oedema
Authority required (STREAMLINED)
6295
Intractable primary menorrhagia
Clinical criteria:
- The treatment must be for the short-term (up to 6 months).

Note
Treatment of this indication is limited to 6 months. See Australian Product Information

6285
Hereditary angio-oedema
Authority required (STREAMLINED)
6295
Intractable primary menorrhagia
Clinical criteria:
- The treatment must be for the short-term (up to 6 months).

Note
Treatment of this indication is limited to 6 months. See Australian Product Information


Danazol 100 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>56.14</td>
<td>38.80</td>
<td>Azol 100 [AF]</td>
</tr>
</tbody>
</table>

Danazol 200 mg capsule, 100

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>80.66</td>
<td>38.80</td>
<td>Azol 200 [AF]</td>
</tr>
</tbody>
</table>

Progesterone receptor modulators

- Mifepristone (&) Misoprostol

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

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

Authority required
Termination of an intra-uterine pregnancy
Clinical criteria:
- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

Treatment criteria:
- Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

Mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>‡1</td>
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<td>38.80</td>
<td>MS-2 Step [XH]</td>
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Urologicals

Drugs for urinary frequency and incontinence

Oxybutynin

Restricted benefit
Detrusor overactivity

Oxybutynin hydrochloride 5 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8039D</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>16.11</td>
<td>* Ditropan [SW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Oxybutynin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

Oxybutynin

Restricted benefit
Detrusor overactivity

Clinical criteria:
- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.
### GENITO URINARY SYSTEM AND SEX HORMONES

#### General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>oxybutynin 3.9 mg/24 hours patch, 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>9454N</td>
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<tr>
<td><strong>Max Qty Packs</strong></td>
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#### PROPANTHELINE

**Restricted benefit**

**Detrusor overactivity**

<table>
<thead>
<tr>
<th>propantheline bromide 15 mg tablet, 100</th>
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<tr>
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<td>2</td>
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#### BICARBONATE

<table>
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<tr>
<td><strong>Max Qty Packs</strong></td>
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</table>

#### PHENOXYBENZAMINE

**Note Continuing Therapy Only:**

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

**Restricted benefit**

**Phaeochromocytoma**

**Restricted benefit**

**Neurogenic urinary retention**

<table>
<thead>
<tr>
<th>phenoxybenzamine hydrochloride 10 mg capsule, 30</th>
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<tbody>
<tr>
<td>1166J</td>
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</tr>
<tr>
<td>3</td>
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<table>
<thead>
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<th>phenoxybenzamine hydrochloride 10 mg capsule, 100</th>
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<td><strong>Max Qty Packs</strong></td>
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<td>1</td>
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<table>
<thead>
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#### DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

**Alpha-adrenoreceptor antagonists**

<table>
<thead>
<tr>
<th>DUTASTERIDE + TAMSLUSIN</th>
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<tbody>
<tr>
<td><strong>Note Continuing Therapy Only:</strong></td>
</tr>
<tr>
<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
</tr>
</tbody>
</table>

**Authority required (STREAMLINED)**

**6189**

**Benign prostatic hyperplasia**

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

<table>
<thead>
<tr>
<th>dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>5490Y</td>
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<tr>
<td><strong>Max Qty Packs</strong></td>
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</tr>
</tbody>
</table>

#### DUTASTERIDE

**Note Continuing Therapy Only:**

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

**Clinical criteria:**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

**dutasteride 500 microgram capsule, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>30.93</td>
<td>32.14</td>
<td></td>
<td>Avodart [GK]</td>
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</tbody>
</table>

**ACTH**

**tetracosactrin 1 mg/mL modified release injection, 1 mL ampoule**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<tr>
<td>5</td>
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<td><strong>449.95</strong></td>
<td>38.80</td>
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<td>Synacthen Depot 1 mg/1 mL [LM]</td>
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**Thyrotropin**

**thyrotropin alfa 900 microgram injection, 2 vials**

<table>
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<td>38.80</td>
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**Vasopressin and analogues**

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>2</td>
<td>5</td>
<td><strong>144.61</strong></td>
<td>38.80</td>
<td></td>
<td>Minirin Nasal Spray [FP]</td>
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</table>

**desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL**

<table>
<thead>
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<th>DPMQ $</th>
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<tr>
<td>5</td>
<td>5</td>
<td><strong>144.75</strong></td>
<td>38.80</td>
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<td>Minirin [FP]</td>
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</table>

**desmopressin acetate 200 microgram tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>3</td>
<td>5</td>
<td><strong>160.90</strong></td>
<td>38.80</td>
<td></td>
<td>Minirin [FP]</td>
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</tbody>
</table>

**Note**

Not to be used in preference to enuresis alarms.

**Note**

Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.
Clinical criteria:
• Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)
5295
Primary nocturnal enuresis

Population criteria:
• Patient must be 6 years of age or older.

Clinical criteria:
• Patient must be one in whom an enuresis alarm is contraindicated.
The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

desmopressin acetate 200 microgram tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>8663Y</td>
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<td>61.03</td>
<td></td>
<td>38.80</td>
<td>Minirin [FP]</td>
</tr>
</tbody>
</table>

• DESMOPRESSIN

Caution Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)
5342
Primary nocturnal enuresis

Population criteria:
• Patient must be 6 years of age or older.

Clinical criteria:
• Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)
5267
Primary nocturnal enuresis

Population criteria:
• Patient must be 6 years of age or older.

Clinical criteria:
• Patient must be one in whom an enuresis alarm is contraindicated.
The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>77.85</td>
<td></td>
<td>38.80</td>
<td>Minirin Nasal Spray [FP]</td>
</tr>
</tbody>
</table>

• DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

Authority required (STREAMLINED)
5412
Primary nocturnal enuresis

Population criteria:
• Patient must be 6 years of age or older.

Clinical criteria:
• Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)
5226
Primary nocturnal enuresis

Population criteria:
• Patient must be 6 years of age or older.

Clinical criteria:
• Patient must be one in whom an enuresis alarm is contraindicated.
The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

desmopressin 120 microgram sublingual wafer, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>66.73</td>
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<td>38.80</td>
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**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

### General

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<th>Brand Name and Manufacturer</th>
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<td>105.68</td>
<td>38.80</td>
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<td>Minirin Melt [FP]</td>
</tr>
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**HYPOTHALAMIC HORMONES**

**Gonadotropin-releasing hormones**

- **NAFARELIN**
  - **Restricted benefit**
  - **Endometriosis**
    - **Treatment Phase:** Initial treatment, for up to 6 months
    - **Clinical criteria:**
      - The condition must be visually proven.
    - **Restricted benefit**
    - **Endometriosis**
      - **Treatment Phase:** Subsequent treatment, for up to 6 months
      - **Clinical criteria:**
        - The condition must be visually proven, **AND**
        - The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
        - Patient must have had a recent bone density assessment.
        - The date of the bone density assessment must be recorded in the patient's medical records.

<table>
<thead>
<tr>
<th>2962X</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>125.06</td>
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<td>Synarel [PF]</td>
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</table>

**CORTICOSTEROIDS FOR SYSTEMIC USE**

**CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN**

**Mineralocorticoids**

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

<table>
<thead>
<tr>
<th>1433K</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>..</td>
<td></td>
<td>*44.89</td>
<td>38.80</td>
<td></td>
<td>Florinef [QA]</td>
</tr>
</tbody>
</table>

**Glucocorticoids**

- **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**
  - **Restricted benefit**
  - **Local intra-articular or peri-articular infiltration**
  - **Restricted benefit**
  - **Keloid**
  - **Restricted benefit**
  - **Lichen planus hypertrophic**

<table>
<thead>
<tr>
<th>5034Y</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td></td>
<td>27.25</td>
<td>28.46</td>
<td></td>
<td>Celestone Chronodose [MK]</td>
</tr>
</tbody>
</table>

- **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**
  - **Note Shared Care Model:**
    - For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  - **Restricted benefit**
    - **Alopecia areata**
  - **Restricted benefit**
    - **Local intra-articular or peri-articular infiltration**
  - **Restricted benefit**
    - **Granulomata**
Clinical criteria:
- The condition must be dermal.

**Restricted benefit**
- Keloid
- Lichen planus hypertrophic
- Lichen simplex chronicus
- Chronic discoid lupus erythematosus
- Necrobiosis lipoidica
- Uveitis

Betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>..</td>
<td>27.25</td>
<td>28.46</td>
<td>Celestone Chronodose [MK]</td>
</tr>
</tbody>
</table>

### CORTISONE

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

cortisone acetate 25 mg tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
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<td>..</td>
<td>23.55</td>
<td>24.76</td>
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</table>

cortisone acetate 5 mg tablet, 50

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>..</td>
<td>18.42</td>
<td>19.63</td>
<td>Cortate [AS]</td>
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### DEXAMETHASONE

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

**DEXAMETHASONE Tablet 500 micrograms, 30**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>13.19</td>
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**DEXAMETHASONE Tablet 4 mg, 30**

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<th>DPMQ $</th>
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<td>16.29</td>
<td>17.50</td>
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**DEXAMETHASONE SODIUM PHOSPHATE**

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

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1291Y</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>20.67</td>
<td>21.88</td>
<td>* Dexamethasone Mylan [AF]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max.Qty</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2509C</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>16.36</td>
<td>17.57</td>
<td>* Dexamethasone Mylan [AF]</td>
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</tbody>
</table>

### HYDROCORTISONE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
hydrocortisone 4 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>4</td>
<td>..</td>
<td>25.55</td>
<td>26.76</td>
<td>Hydrocortisone 4 [AF]</td>
</tr>
</tbody>
</table>

hydrocortisone 20 mg tablet, 60

<table>
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<tr>
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<td>31.73</td>
<td>32.94</td>
<td>Hydrocortisone 20 [AF]</td>
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**HYDROCORTISONE SODIUM SUCCINATE**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*20.89</td>
<td>22.10</td>
<td>Solu-Cortef [PF]</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>19.85</td>
<td>21.06</td>
<td>Solu-Cortef [PF]</td>
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</table>

**HYDROCORTISONE SODIUM SUCCINATE**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>6</td>
<td>..</td>
<td>..</td>
<td>*40.51</td>
<td>38.80</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>..</td>
<td>..</td>
<td>*63.67</td>
<td>38.80</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

methylprednisolone Powder for injection 1 g (as sodium succinate), 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>43.59</td>
<td>38.80</td>
<td>Methylpred [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Methylprednisolone Alphapharm [AF]</td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

Restricted benefit

methylprednisolone Powder for injection 1 g (as sodium succinate), 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>23.23</td>
<td>24.44</td>
<td>Methylpred [AL]</td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

Restricted benefit

methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>22.47</td>
<td>23.68</td>
<td>Depo-Nisolone [FZ]</td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

Note Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

methylprednisolone Powder for injection 40 mg (as sodium succinate), 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>23.23</td>
<td>24.44</td>
<td>Methylpred [AL]</td>
</tr>
</tbody>
</table>
# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

**METHYPREDNISOLONE**

Restricted benefit
Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

<table>
<thead>
<tr>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22.47</td>
<td>23.68</td>
<td></td>
</tr>
</tbody>
</table>

* Depo-Nisolone [FZ]

**PREDNISOLONE**

prednisolone 1 mg tablet, 100

<table>
<thead>
<tr>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>4</td>
<td>13.65</td>
<td>14.86</td>
<td></td>
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</table>

* Predsolone [LN]

**PREDNISONE**

prednisone 1 mg tablet, 100

<table>
<thead>
<tr>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>4</td>
<td>13.60</td>
<td>14.81</td>
<td></td>
</tr>
</tbody>
</table>

* Predsone [LN]

**TRIAMCINOLONE**

Restricted benefit
Local intra-articular or peri-articular infiltration

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

<table>
<thead>
<tr>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>27.25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Kenacort-A10 [QA]
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Restricted benefit
Alopecia areata

Restricted benefit
Local intra-articular or peri-articular infiltration

Restricted benefit
Granulomata
Clinical criteria:
- The condition must be dermal.

Restricted benefit
Keloid

Restricted benefit
Lichen planus hypertrophic

Restricted benefit
Lichen simplex chronicus

Restricted benefit
Chronic discoid lupus erythematosus

Restricted benefit
Necrobiosis lipoidica

Restricted benefit
Psoriasis

Trianclitriolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
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<td>28.46</td>
<td>Kenacort-A10 [QA]</td>
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</tbody>
</table>

THYROID THERAPY

THYROID PREPARATIONS

THYROID THERAPY

THYROID THERAPY

LIOTHYRONINE

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

Authority required (STREAMLINED)
6382
Thyroid cancer

Authority required (STREAMLINED)
6410
Hypothyroidism
Clinical criteria:
- The treatment must be for replacement therapy, AND
- Patient must have documented intolerance to thyroxine sodium; OR
- Patient must have documented resistance to thyroxine sodium.

 Authority required (STREAMLINED)
6475
Hypothyroidism
Clinical criteria:
- The condition must be severe hypothyroidism, AND
- The treatment must be for initiation of therapy only.

Liothryronine sodium 20 microgram tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
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<td>77.69</td>
<td>38.80</td>
<td>Tertroxin [QA]</td>
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</table>

THYROXINE

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

Thyroxine sodium 75 microgram tablet, 200

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>9287T</td>
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<td>1</td>
<td>26.39</td>
<td>27.60</td>
<td>Eutroxsig [FM]</td>
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<tr>
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<td></td>
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<td>1.98</td>
<td>28.37</td>
<td>Oroxine [QA]</td>
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</table>
sysyemc hormonal preparations, excl. sex hormones and insulins

thyroxine sodium 100 microgram tablet, 200

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>26.36</td>
<td>27.57</td>
<td>* Eutroxsig [FM]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>8*1.92</td>
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thyroxine sodium 200 microgram tablet, 200

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>1</td>
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<td>28.99</td>
<td>30.20</td>
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<td>8*1.93</td>
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thyroxine sodium 50 microgram tablet, 200

<table>
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<td>8*1.91</td>
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</table>

ANTITHYROID PREPARATIONS

Thiouracils

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

propylthiouracil 50 mg tablet, 100

<table>
<thead>
<tr>
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<tbody>
<tr>
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<td>2</td>
<td>..</td>
<td>47.89</td>
<td>38.80</td>
<td>PTU [PL]</td>
</tr>
</tbody>
</table>

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

carbimazole 5 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>31.41</td>
<td>32.62</td>
<td>Carbimazol ARISTO [PQ]</td>
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<td></td>
<td></td>
<td></td>
<td>Neo-Mercazole [GH]</td>
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</tbody>
</table>

GLYCOGENOLYTIC HORMONES

Glycogenolytic hormones

- GLUCAGON HYDROCHLORIDE

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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<td>1</td>
<td>..</td>
<td>50.97</td>
<td>38.80</td>
<td>GlucaGen Hypokit [NO]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td></td>
<td>50.97</td>
<td>38.80</td>
<td>GlucaGen Hypokit [NO]</td>
</tr>
</tbody>
</table>

CALCIUM HOMEOSTASIS

- PARATHYROID HORMONES AND ANALOGUES
  Parathyroid hormones and analogues

TERIPARATIDE

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required
Severe established osteoporosis
Treatment Phase: Initial treatment
Treatment criteria:
• Must be treated by a specialist; OR
• Must be treated by a consultant physician.

Clinical criteria:
• Patient must be at very high risk of fracture, AND
• Patient must have a bone mineral density (BMD) T-score of -3.0 or less, AND
• Patient must have had 2 or more fractures due to minimal trauma, AND
• Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, AND
• The treatment must be the sole PBS-subsidised agent, AND
• The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required
Severe established osteoporosis
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously been issued with an authority prescription for this drug, AND
• The treatment must not exceed a lifetime maximum of 18 months therapy.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

### teriparatide 20 microgram injection, 2.4 mL cartridge

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>411.80</td>
<td>38.80</td>
<td></td>
<td>Forteo [LY]</td>
</tr>
</tbody>
</table>

### ANTI-PARATHYROID AGENTS

#### Calcitonin preparations

**SALCATONIN**

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

[Restricted benefit]
Symptomatic Paget disease of bone

[Restricted benefit]
Hypercalcaemia

Clinical criteria:
The treatment must be initiated in a hospital.

### salcatonin 100 units/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*144.67</td>
<td>38.80</td>
<td></td>
<td>Miacalcic 100 [NV]</td>
</tr>
</tbody>
</table>

### ANTIINFECTIVES FOR SYSTEMIC USE

### ANTIBACTERIALS FOR SYSTEMIC USE

#### TETRACYCLINES

**Tetracyclines**
### DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

<table>
<thead>
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<th>Product Description</th>
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<th>MRVSN $</th>
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<td><em>Doryx [YN]</em></td>
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</table>

### DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

**Restricted benefit**

Urethritis

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### DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

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#### Restricted benefit

Severe acne

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| Reduced benefit |

Severe acne

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#### Restricted benefit

Pelvic inflammatory disease

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#### Restricted benefit

Bronchiectasis

Population criteria:
- Patient must be aged 8 years or older.

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#### Restricted benefit

Chronic bronchitis

Population criteria:
- Patient must be aged 8 years or older.

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#### Restricted benefit

Severe acne

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### Doxycycline 50 mg Modified Release Capsule, 25

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### Doxycycline 50 mg Tablet, 25

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### Doxycycline 50 mg Tablet, 25

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<td>14.63</td>
<td></td>
<td>DDMVX [BW]</td>
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</tbody>
</table>

### Minocycline

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

### Restricted Benefit

Severe acne

**Clinical criteria:**

- The condition must not be responding to other tetracyclines.

### Minocycline 50 mg Tablet, 60

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### Beta-Lactam Antibacterials, Penicillins

**Penicillins with extended spectrum**

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<td>Amoxicillin Sandoz [SZ]</td>
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### Amoxicillin 500 mg Capsule, 20

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### Amoxicillin 500 mg/5 mL Powder for Oral Liquid, 100 mL

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### Amoxicillin 500 mg/5 mL Powder for Oral Liquid, 100 mL

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<td>17.20</td>
<td></td>
<td>Maxamox [SZ]</td>
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</tbody>
</table>
## AMOXICILLIN

### Restricted benefit

**Chronic bronchitis**

- Patient must have acute exacerbations of the condition.

### AMOXICILLIN

#### Authority required

Infection suspected or proven to be due to a susceptible organism

---

**amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL**

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**amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL**

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<td></td>
<td></td>
<td>APO-Amoxycillin [TX]</td>
<td>Cilamox [QA]</td>
</tr>
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<td>Ranmoxy [RA]</td>
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<td>Amoxil Forte [AS]</td>
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</tbody>
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**amoxycillin 100 mg/mL powder for oral liquid, 20 mL**

<table>
<thead>
<tr>
<th>Code</th>
<th>Schedule</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1888J</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0.53</td>
<td>18.03</td>
<td>19.07</td>
<td>Amoxil [AS]</td>
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**amoxycillin 250 mg capsule, 20**

<table>
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<td>Alphamox 125 [AF]</td>
<td>Amoxycillin Sandoz [SZ]</td>
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<tr>
<td></td>
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<td>APO-Amoxycillin [TX]</td>
<td>Ranmoxy [RA]</td>
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<td></td>
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<td>Amoxil [AS]</td>
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</tbody>
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**amoxycillin 100 mg/mL powder for oral liquid, 20 mL**

<table>
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<tr>
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**amoxycillin 125 mg/5 mL powder for oral liquid, 100 mL**

<table>
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<td>Alphamox 125 [AF]</td>
<td>Amoxycillin Sandoz [SZ]</td>
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<td></td>
<td></td>
<td>APO-Amoxycillin [TX]</td>
<td>Ranmoxy [RA]</td>
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<td>Amoxil [AS]</td>
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**amoxycillin 125 mg/5 mL powder for oral liquid, 100 mL**

<table>
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<tr>
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<th>Schedule</th>
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<td>Amoxycillin Sandoz [SZ]</td>
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<td>APO-Amoxycillin [TX]</td>
<td>Ranmoxy [RA]</td>
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<td>Amoxil [AS]</td>
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**amoxycillin 250 mg capsule, 20**

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<th>Brand Name and Manufacturer</th>
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<td>Amoxil [AS]</td>
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**amoxycillin 250 mg capsule, 20**

<table>
<thead>
<tr>
<th>Code</th>
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<th>MRVSN ($)</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
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<td>1</td>
<td>15.98</td>
<td>13.70</td>
<td>-</td>
<td>Amoxil [AS]</td>
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**amoxycillin 100 mg/mL powder for oral liquid, 20 mL**

<table>
<thead>
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<th>Code</th>
<th>Schedule</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>8581P</td>
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<td>13.75</td>
<td>13.88</td>
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<td>Amoxycillin Sandoz [SZ]</td>
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</tr>
</tbody>
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**amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL**

<table>
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<tr>
<th>Code</th>
<th>Schedule</th>
<th>Max Qty Packs</th>
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<tbody>
<tr>
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<td>1</td>
<td>13.75</td>
<td>13.88</td>
<td>-</td>
<td>Amoxycillin Sandoz [BG]</td>
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**amoxycillin 1 g tablet, 14**

<table>
<thead>
<tr>
<th>Code</th>
<th>Schedule</th>
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<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>13.75</td>
<td>13.88</td>
<td>-</td>
<td>Amoxycillin Sandoz [BG]</td>
<td></td>
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**amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL**

<table>
<thead>
<tr>
<th>Code</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>1</td>
<td>13.75</td>
<td>13.88</td>
<td>-</td>
<td>Amoxycillin Sandoz [BG]</td>
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**amoxycillin 1 g tablet, 14**

<table>
<thead>
<tr>
<th>Code</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>13.75</td>
<td>13.88</td>
<td>-</td>
<td>Amoxycillin Sandoz [BG]</td>
<td></td>
</tr>
</tbody>
</table>
Clinical criteria:
- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

**AMPCILLIN**

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9714G</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>#18.03</td>
<td>Amoxil [AS]</td>
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</tbody>
</table>

**AMPICILLIN**

amoxicillin 500 mg injection, 5 vials

<table>
<thead>
<tr>
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<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2390T</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>16.05</td>
<td>Austrapen [AL]</td>
</tr>
</tbody>
</table>

amoxicillin 500 mg injection, 5 vials

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3313J</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>16.05</td>
<td>Austrapen [AL]</td>
</tr>
</tbody>
</table>

amoxicillin 1 g injection, 5 vials

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2977Q</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>17.23</td>
<td>*Ampicyn [AF]</td>
</tr>
</tbody>
</table>

amoxicillin 1 g injection, 5 vials

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3314K</td>
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<td>17.23</td>
<td>18.44</td>
<td>*Ampicyn [AF]</td>
</tr>
</tbody>
</table>

**BETAZATHINE BENZYLPEICILLIN**

BETAZATHINE BENZYLPEICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>2267H</td>
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<td>..</td>
<td>309.22</td>
<td>38.80</td>
<td>Bicillin L-A [PF]</td>
</tr>
</tbody>
</table>

BETAZATHINE BENZYLPEICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
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<td>309.22</td>
<td>38.80</td>
<td>Bicillin L-A [PF]</td>
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</tbody>
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**BENZYLPEICILLIN**

benzylpenicillin 600 mg injection, 1 vial

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<td>1775K</td>
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<td>*61.35</td>
<td>38.80</td>
<td>BenPen [CS]</td>
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benzylpenicillin 600 mg injection, 1 vial

<table>
<thead>
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<th>Max Qty Packs</th>
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<td>*61.35</td>
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<td>BenPen [CS]</td>
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benzylpenicillin 3 g injection, 1 vial

<table>
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<tbody>
<tr>
<td>2647H</td>
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<td>*97.95</td>
<td>38.80</td>
<td>BenPen [CS]</td>
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benzylpenicillin 3 g injection, 1 vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
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<tbody>
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<td>3399X</td>
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<td>*97.95</td>
<td>38.80</td>
<td>BenPen [CS]</td>
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</table>

**PHENOXYMETHYLPENICILLIN**

phenoxyethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<tbody>
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<td>*#20.56</td>
<td>22.13</td>
<td>Phenoxyethylpenicillin-AFT [AE]</td>
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</table>

phenoxyethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
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<tbody>
<tr>
<td>8976K</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*#20.56</td>
<td>Phenoxyethylpenicillin-AFT [AE]</td>
</tr>
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</table>
## PHENOXYMETHYLPENICILLIN

**Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**
- The treatment must be for prophylaxis.

### phenoxymethylpenicillin 250 mg tablet, 25

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Aspecillin VK [QA]</td>
<td>*15.35</td>
<td>16.56</td>
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### phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

<table>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Phenoxymethylpenicillin-AFT [AE]</td>
<td>*22.80</td>
<td>24.37</td>
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</tr>
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</table>

### phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

<table>
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<tbody>
<tr>
<td>Cilicaine V [FM]</td>
<td>*24.29</td>
<td>25.50</td>
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### phenoxymethylpenicillin 250 mg tablet, 25

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Aspecillin VK [QA]</td>
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<td>18.60</td>
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### phenoxymethylpenicillin 500 mg tablet, 25

<table>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Cilicaine V [FM]</td>
<td>*15.21</td>
<td>16.42</td>
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### phenoxymethylpenicillin 500 mg capsule, 50

<table>
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<th>DPMQ</th>
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<tbody>
<tr>
<td>Cilicaine V [FM]</td>
<td>17.22</td>
<td>18.43</td>
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### phenoxymethylpenicillin 250 mg capsule, 50

<table>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>Cilicaine VK [FM]</td>
<td>15.21</td>
<td>16.42</td>
<td></td>
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</tbody>
</table>

### PHENOXYMETHYLPENICILLIN

**Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**
- The treatment must be for prophylaxis.
### PROCAINE PENICILLIN
procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>Cilicaine [QA]</td>
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</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3371K</td>
<td>1</td>
<td>..</td>
<td>85.18</td>
<td>38.80</td>
<td></td>
<td>Cilicaine [QA]</td>
</tr>
</tbody>
</table>

### DICLOXACILLIN

#### Restricted benefit
Serious staphylococcal infection

**dicloxacillin 500 mg capsule, 24**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5097G</td>
<td>1</td>
<td>..</td>
<td>20.73</td>
<td>21.94</td>
<td></td>
<td>Distaph 500 [AF]</td>
</tr>
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</table>

**dicloxacillin 250 mg capsule, 24**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5096F</td>
<td>1</td>
<td>..</td>
<td>16.60</td>
<td>17.81</td>
<td></td>
<td>Distaph 250 [AF]</td>
</tr>
</tbody>
</table>

### DICLOXACILLIN

#### Authority required (STREAMLINED)

**6188 Osteomyelitis**

**dicloxacillin 500 mg capsule, 24**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>..</td>
<td>20.73</td>
<td>21.94</td>
<td></td>
<td>Distaph 500 [AF]</td>
</tr>
</tbody>
</table>

**dicloxacillin 250 mg capsule, 24**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8121K</td>
<td>1</td>
<td>..</td>
<td>16.60</td>
<td>17.81</td>
<td></td>
<td>Distaph 250 [AF]</td>
</tr>
</tbody>
</table>

### DICLOXACILLIN

#### Caution
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Note** Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

**flucloxacillin 1 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10605E</td>
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<td>1</td>
<td>*19.46</td>
<td>20.67</td>
<td></td>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

**flucloxacillin 1 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10609J</td>
<td>0.5</td>
<td>..</td>
<td>*19.46</td>
<td>20.67</td>
<td></td>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

**flucloxacillin 1 g injection, 5 vials**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1525G</td>
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<td>..</td>
<td>16.41</td>
<td>17.62</td>
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<td>Flucil [AS]</td>
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</tbody>
</table>

**flucloxacillin 1 g injection, 5 vials**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5095E</td>
<td>1</td>
<td>..</td>
<td>16.41</td>
<td>17.62</td>
<td></td>
<td>Flucil [AS]</td>
</tr>
</tbody>
</table>
**FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**
Serious staphylococcal infection

**FLUCLOXACILLIN**

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**
Serious staphylococcal infection

**FLUCLOXACILLIN**

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Authority required (STREAMLINED)**

**Combinations of penicillins, incl. beta-lactamase inhibitors**
ANTIINFECTIVES FOR SYSTEMIC USE

**AMOXYCILLIN + CLAVULANIC ACID**

Caution Hepatotoxicity has been reported with this drug.

- **Restricted benefit**
  - Infection where resistance to amoxycillin is suspected
  - Infections where resistance to amoxycillin is proven

---

**amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>£1</td>
<td>1</td>
<td>.</td>
<td>#15.86</td>
<td>17.43</td>
<td>* APO-Amoxycillin and Clavulanic Acid 400/57 [TX]</td>
<td>* Curam Duo [SZ]</td>
</tr>
</tbody>
</table>

---

**amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>£1</td>
<td>1</td>
<td>.</td>
<td>#15.54</td>
<td>17.11</td>
<td>* AlphaClav Duo [AF]</td>
<td>* APO-Amoxycillin/ Clavulanic Acid 500/125 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* AMCLAFOX DUO 500/125 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* AMCLAFOX DUO 500/125 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Curam Duo 500/125 [SZ]</td>
</tr>
</tbody>
</table>

---

**amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>£1</td>
<td>1</td>
<td>.</td>
<td>#15.54</td>
<td>17.11</td>
<td>* APO-Amoxycillin and Clavulanic Acid 125/31.25 [TX]</td>
<td>* Curam [SZ]</td>
</tr>
</tbody>
</table>

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**amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>£1</td>
<td>1</td>
<td>.</td>
<td>#15.86</td>
<td>17.43</td>
<td>* AlphaClav Duo Forte [AF]</td>
<td>* AMCLAFOX DUO FORTE 875/125 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* AMCLAFOX DUO FORTE 875/125 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Moxiclav Duo Forte 875/125 [QA]</td>
</tr>
</tbody>
</table>

---

**AMOXYCILLIN + CLAVULANIC ACID**

Caution Hepatotoxicity has been reported with this drug.

- **Restricted benefit**
  - Infection where resistance to amoxycillin is suspected
  - Infections where resistance to amoxycillin is proven

---
**ANTIINFECTIVES FOR SYSTEMIC USE**

<table>
<thead>
<tr>
<th>amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>5009P</td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<tr>
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</tr>
<tr>
<td>$1</td>
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<tr>
<td>$3.45</td>
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</table>

<table>
<thead>
<tr>
<th>amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>5006L</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---</td>
</tr>
</tbody>
</table>

### TICARcILLIN + CLAVULANIC ACID

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

<table>
<thead>
<tr>
<th>ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>10125X</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

#### TICARcILLIN + CLAVULANIC ACID

**Note Shared Care Model:**

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

#### Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit

Septicaemia, suspected

<table>
<thead>
<tr>
<th>ticarcillin 3 g + clavulanic acid 100 mg injection, 3.1 g vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>10113G</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

### OTHER BETA-LACTAM ANTIBACTERIALS

**First-generation cephalosporins**

<table>
<thead>
<tr>
<th>CEPHALEXIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>cephalaxin 250 mg capsule, 20</td>
</tr>
<tr>
<td>3058Y</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---</td>
</tr>
</tbody>
</table>

#### 3.76 |

<table>
<thead>
<tr>
<th>cephalaxin 250 mg capsule, 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>3317N</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---</td>
</tr>
</tbody>
</table>

#### 3.76
### ANTIIINFECTIVES FOR SYSTEMIC USE

#### CEPHALEXIN

| Authority required (STREAMLINED) | 6188 Osteomyelitis | 4243 Prophylaxis of urinary tract infection |

#### CEPHALEXIN

| CEPHALEXIN  | Authority required (STREAMLINED) | 6188 Osteomyelitis | 4243 Prophylaxis of urinary tract infection |

| CEPHALEXIN  | Authority required (STREAMLINED) | 6188 Osteomyelitis | 4243 Prophylaxis of urinary tract infection |

| cephalixin 500 mg capsule, 20 |
| --- | --- | --- | --- |
| 3119E | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 1 | 1 | .. | 12.95 | 14.16 | * APO-Cephalexin [TX] | * Cefalexin Sandoz [SZ] |
| * Ibilex 500 [AF] | * Rancef [RA] | |

| cephalixin 500 mg capsule, 20 |
| --- | --- | --- | --- |
| 3318P | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 1 | . | . | 12.95 | 14.16 | * APO-Cephalexin [TX] | * Cefalexin Sandoz [SZ] |
| * Ibilex 500 [AF] | * Rancef [RA] | |

| cephalixin 125 mg/5 mL powder for oral liquid, 100 mL |
| --- | --- | --- | --- |
| 3094W | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| ↓1 | 1 | .. | #15.78 | 17.35 | * APO-Cephalexin [TX] | * Cefalexin Sandoz [SZ] |
| * Ibilex 125 [AF] | |

| cephalixin 125 mg/5 mL powder for oral liquid, 100 mL |
| --- | --- | --- | --- |
| 3319Q | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| ↓1 | . | . | #15.78 | 17.35 | * APO-Cephalexin [TX] | * Cefalexin Sandoz [SZ] |
| * Ibilex 125 [AF] | |

| cephalixin 250 mg/5 mL powder for oral liquid, 100 mL |
| --- | --- | --- | --- |
| 3095X | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| ↓1 | 1 | .. | #16.08 | 17.65 | * APO-Cephalexin [TX] | * Cefalexin Sandoz [SZ] |
| 5.69 | #21.77 | 17.65 | * Keflex [AS] | * Chem mart Cephalexin [CH] | * Terry White Chemists Cephalexin [TW] |
| * Ibilex 250 [AF] | |

| cephalixin 250 mg/5 mL powder for oral liquid, 100 mL |
| --- | --- | --- | --- |
| 3320R | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| ↓1 | . | . | #16.08 | 17.65 | * APO-Cephalexin [TX] | * Cefalexin Sandoz [SZ] |
| 5.69 | #21.77 | 17.65 | * Keflex [AS] | * Chem mart Cephalexin [CH] | * Terry White Chemists Cephalexin [TW] |
| * Ibilex 250 [AF] | |

---

General Pharmaceutical Benefits 209
### CEPHALOTHIN

**cephalothin 1 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2964B</td>
<td>1</td>
<td>..</td>
<td>25.56</td>
<td>26.77</td>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

**cephalothin 1 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3376Q</td>
<td>1</td>
<td>..</td>
<td>25.56</td>
<td>26.77</td>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

### CEPHAZOLIN

**Restricted benefit**

**Cellulitis**

**cephazolin 500 mg injection, 5 vials**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5477G</td>
<td>2</td>
<td>..</td>
<td>*17.39</td>
<td>18.60</td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

**cephazolin 2 g injection, 1 vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5479J</td>
<td>10</td>
<td>..</td>
<td>*38.85</td>
<td>38.80</td>
<td>Cephazolin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

### CEPHAZOLIN

**Note** For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Restricted benefit**

**Cellulitis**

**cephazolin 1 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5478H</td>
<td>1</td>
<td>..</td>
<td>20.87</td>
<td>22.08</td>
<td>* Cefazolin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**cephazolin 1 g injection, 5 vials**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1799Q</td>
<td>2</td>
<td>..</td>
<td>*20.87</td>
<td>22.08</td>
<td>* Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

### CEPHAZOLIN

**Note Shared Care Model:**

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

**Restricted benefit**

**Infection** where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

**Septicaemia, suspected**

**Restricted benefit**

**Septicaemia, proven**

**cephazolin 500 mg injection, 5 vials**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1256D</td>
<td>2</td>
<td>..</td>
<td>*17.39</td>
<td>18.60</td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

**cephazolin 2 g injection, 1 vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9326W</td>
<td>10</td>
<td>..</td>
<td>*38.85</td>
<td>38.80</td>
<td>Cephazolin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

### CEPHAZOLIN

**Note** For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note Shared Care Model:**

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

### Restricted benefit
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

### Restricted benefit
Septicaemia, suspected

### Restricted benefit
Septicaemia, proven

<table>
<thead>
<tr>
<th>cepazolin 1 g injection, 10 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1257E Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cepazolin 1 g injection, 5 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1797N Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

### Second-generation cephalosporins

#### CEFACLOR

**Caution** Serum sickness-like reactions have been reported with this drug, especially in children.

<table>
<thead>
<tr>
<th>cefaclor 375 mg modified release tablet, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1169M Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>cefaclor 375 mg modified release tablet, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>5045M Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cefaclor 250 mg/5 mL powder for oral liquid, 75 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2461M Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cefaclor 250 mg/5 mL powder for oral liquid, 75 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>5047P Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cefaclor 125 mg/5 mL powder for oral liquid, 100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2460L Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cefaclor 125 mg/5 mL powder for oral liquid, 100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>5046N Max Qty Packs</td>
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<tr>
<td>1</td>
</tr>
</tbody>
</table>

#### CEFUROXIME

<table>
<thead>
<tr>
<th>cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL</th>
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</thead>
<tbody>
<tr>
<td>11191B Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>11192C Max Qty Packs</td>
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<tr>
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</table>
ANTIIINFECTIVES FOR SYSTEMIC USE

**Cefuroxime 250 mg tablet, 14**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Cefuroxime 250 mg tablet, 14**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Cefuroxime 250 mg injection, 1 vial**

<table>
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<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefuroxine-PT [AE]</td>
<td>1</td>
<td>1</td>
<td>12.15</td>
<td>13.36</td>
<td>Cefuroxine-PT [AE]</td>
<td></td>
</tr>
</tbody>
</table>

**Third-generation cephalosporins**

**CEFOTAXIME**

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**CEFOTAXIME Powder for injection 1 g, 10**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospira Pty Limited [PF]</td>
<td>1</td>
<td>10</td>
<td>23.88</td>
<td>25.09</td>
<td>Hospira Pty Limited [PF]</td>
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</table>

**CEFOTAXIME Powder for injection 2 g, 10**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospira Pty Limited [PF]</td>
<td>1</td>
<td>10</td>
<td>34.74</td>
<td>35.95</td>
<td>Hospira Pty Limited [PF]</td>
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**CEFOTAXIME**

**Note Shared Care Model:**

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

**CEFOTAXIME Powder for injection 1 g, 10**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Hospira Pty Limited [PF]</td>
<td>1</td>
<td>10</td>
<td>23.88</td>
<td>25.09</td>
<td>Hospira Pty Limited [PF]</td>
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**CEFOTAXIME Powder for injection 2 g, 10**

<table>
<thead>
<tr>
<th></th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Hospira Pty Limited [PF]</td>
<td>1</td>
<td>10</td>
<td>34.74</td>
<td>35.95</td>
<td>Hospira Pty Limited [PF]</td>
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</table>

**CEFTRIAXONE**

**Restricted benefit**

Gonorrhoea

**CEFTRIAXONE Powder for injection 500 mg injection, 1 vial**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone-AFT [AE]</td>
<td>1</td>
<td>1</td>
<td>12.15</td>
<td>13.36</td>
<td>Ceftriaxone-AFT [AE]</td>
<td></td>
</tr>
</tbody>
</table>

**CEFTRIAXONE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

**ceftriaxone 500 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*16.40</td>
<td>17.61</td>
<td>Ceftriaxone-AFT [AE]</td>
</tr>
</tbody>
</table>

**CEFTRIAXONE**

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 1 vial and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials are equivalent for the purposes of substitution.

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

**ceftriaxone 2 g injection, 1 vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*22.25</td>
<td>23.46</td>
<td>* Ceftriaxone-AFT [AE]</td>
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</table>

**CEFTRIAXONE 2 g injection, 5 vials**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>22.22</td>
<td>23.43</td>
<td>* Ceftriaxone Alphapharm [AF]</td>
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</tbody>
</table>

**CEFTRIAXONE**

**Note** For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

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

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

**ceftriaxone 1 g injection, 1 vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*22.10</td>
<td>23.31</td>
<td>* Ceftriaxone-AFT [AE]</td>
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</table>

**CEFTRIAXONE Powder for injection 1 g, 5**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>22.11</td>
<td>23.32</td>
<td>* Ceftriaxone Alphapharm [AF]</td>
</tr>
</tbody>
</table>

**Fourth-generation cephalosporins**

**CEFEPIME**

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

**Authority required**
Febrile neutropenia
ANTIINFECTIVES FOR SYSTEMIC USE

CEFEPI ME Powder for injection 2 g (as hydrochloride), 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resprim Forte [AF]</td>
<td>129.55</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>DBL Cefepime [PF]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CEFEPI ME Powder for injection 1 g (as hydrochloride), 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resprim Forte [AF]</td>
<td>79.35</td>
<td>38.80</td>
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</tr>
<tr>
<td>DBL Cefepime [PF]</td>
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<td></td>
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</tbody>
</table>

SULFONAMIDES AND TRIMETHOPRIM

TRIMETHOPRIM

trimethoprim 300 mg tablet, 7

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprim [AF]</td>
<td>12.79</td>
<td>14.00</td>
<td></td>
</tr>
<tr>
<td>Triprim [RW]</td>
<td></td>
<td>14.00</td>
<td></td>
</tr>
</tbody>
</table>

TRIMETHOPRIM

Authority required (STREAMLINED)

trimethoprim 300 mg tablet, 7

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Alprim [AF]</td>
<td>14.49</td>
<td>15.70</td>
<td></td>
</tr>
<tr>
<td>Triprim [RW]</td>
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<td>15.70</td>
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</table>

TRIMETHOPRIM

Restricted benefit

trimethoprim 300 mg tablet, 7

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprim [AF]</td>
<td>17.91</td>
<td>19.12</td>
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</tr>
</tbody>
</table>

TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bactrim [RO]</td>
<td>13.27</td>
<td>14.48</td>
<td></td>
</tr>
<tr>
<td>Septrin [RW]</td>
<td></td>
<td>14.48</td>
<td></td>
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</tbody>
</table>

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bactrim [RO]</td>
<td>13.27</td>
<td>14.48</td>
<td></td>
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<tr>
<td>Septrin [RW]</td>
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<td>14.48</td>
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</table>

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>Resprim Forte [AF]</td>
<td>12.98</td>
<td>14.19</td>
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<tr>
<td>Bactrim DS [RO]</td>
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</table>

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
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<tbody>
<tr>
<td>Resprim Forte [AF]</td>
<td>12.98</td>
<td>14.19</td>
<td></td>
</tr>
<tr>
<td>Bactrim DS [RO]</td>
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</tbody>
</table>

TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.
antiinfectives for systemic use

**General Pharmaceutical Benefits** 215

Authority required (STREAMLINED)

**6201**
Prophylaxis of Pneumocystis jiroveci pneumonia

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>3</td>
<td>2</td>
<td>..</td>
<td>*16.75</td>
<td>17.96</td>
<td>* Resprim Forte [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>6.51</td>
<td>23.26</td>
<td>* Bactrim DS [RO]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>12.51</td>
<td>29.26</td>
<td>* Septin Forte [RW]</td>
</tr>
</tbody>
</table>

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

**Macrolides**

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

  Restricted benefit

  **Trachoma**

  azithromycin 500 mg tablet, 2

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td></td>
<td></td>
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</tr>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>15.37</td>
<td>16.58</td>
<td>* APO-Azithromycin [TX]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Azithromycin Mylan [AF]</td>
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<td></td>
<td></td>
<td></td>
<td>* Azithromycin Sandoz [SZ]</td>
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<td></td>
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<td></td>
<td>* Terry White Chemists</td>
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<td></td>
<td>* Azithromycin [TW]</td>
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<td></td>
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<td></td>
<td>* Azithromycin Mylan [AF]</td>
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<td></td>
<td></td>
<td>* Azithromycin Mylan [AF]</td>
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<td></td>
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<td></td>
<td>* Chem mart Azithromycin [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>* Zithromax [PF]</td>
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</table>

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>A</td>
<td>..</td>
<td>..</td>
<td>#26.26</td>
<td>27.83</td>
<td>Zithromax [PF]</td>
</tr>
</tbody>
</table>

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

  Restricted benefit

  **Urethritis**

  **Clinical criteria:**

  - The condition must be uncomplicated and due to Chlamydia trachomatis.

  Restricted benefit

  **Cervicitis**

  **Clinical criteria:**

  - The condition must be uncomplicated and due to Chlamydia trachomatis.

azithromycin 500 mg tablet, 2

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>8200N</td>
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<td>15.37</td>
<td>16.58</td>
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<tr>
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<td></td>
<td></td>
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</tr>
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<td></td>
<td>* Terry White Chemists</td>
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<td>* Azithromycin [TW]</td>
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<tr>
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<td></td>
<td>* Azithromycin Mylan [AF]</td>
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<td></td>
<td></td>
<td>* Chem mart Azithromycin [CH]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>* Zithromax [PF]</td>
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- **CLARITHROMYCIN**
  
  clarithromycin 250 mg tablet, 14

<table>
<thead>
<tr>
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<td>1</td>
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<td>* APO-Clarithromycin [TX]</td>
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<td>* Chem mart Clarithromycin</td>
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<td></td>
<td>* Clarithromycin [CH]</td>
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<td>* Clarithral [HX]</td>
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<td>* Clarithromycin AN [EA]</td>
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<td>* Kalixocin [AF]</td>
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<td>* Kalixocin [AF]</td>
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**CLARITHROMYCIN**

Restricted benefit

Bordetella pertussis

Restricted benefit

Atypical mycobacterial infections
clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>†1</td>
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<td>#29.93</td>
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**ERYTHROMYCIN**

erythromycin 250 mg enteric capsule, 25

<table>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>15.87</td>
<td>17.08</td>
<td>* Mayne Pharma Erythromycin [YT]</td>
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<tr>
<td></td>
<td></td>
<td>#2.53</td>
<td>18.40</td>
<td>* Eryc [YN]</td>
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erythromycin 250 mg enteric capsule, 25

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<td>#2.53</td>
<td>18.40</td>
<td>* Eryc [YN]</td>
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</tr>
</tbody>
</table>

**ERYTHROMYCIN**

Authority required (STREAMLINED)

6160
Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.

erythromycin 250 mg enteric capsule, 25

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>21.86</td>
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**ERYTHROMYCIN ETHYLSUCCINATE**

erythromycin (as ethylsuccinate) 400 mg tablet, 25

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
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<td>15.99</td>
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<td>E-Mycin [AF]</td>
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erythromycin (as ethylsuccinate) 400 mg tablet, 25

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td>15.99</td>
<td>17.20</td>
<td>E-Mycin [AF]</td>
<td></td>
</tr>
</tbody>
</table>

erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td>#18.62</td>
<td>20.19</td>
<td>* E-Mycin 200 [AF]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.36</td>
<td>#20.98</td>
<td>20.19</td>
<td>* E.E.S. 200 [GH]</td>
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</table>

erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
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<tr>
<td></td>
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<td>2.36</td>
<td>#20.98</td>
<td>20.19</td>
<td>* E.E.S. 200 [GH]</td>
</tr>
</tbody>
</table>

erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL

<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
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<td>#19.93</td>
<td>21.50</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>2.38</td>
<td>#22.31</td>
<td>21.50</td>
<td>* E.E.S. Granules [GH]</td>
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</table>

erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<tr>
<td></td>
<td></td>
<td>2.38</td>
<td>#22.31</td>
<td>21.50</td>
<td>* E.E.S. Granules [GH]</td>
</tr>
</tbody>
</table>

**ERYTHROMYCIN ETHYLSUCCINATE**

Authority required (STREAMLINED)

6160
Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.
### Antiinfectives for Systemic Use

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>E-Mycin [AF]</td>
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#### Roxithromycin

**Roxithromycin 150 mg tablet, 10**

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<tbody>
<tr>
<td>APO-Roxithromycin [TX]</td>
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<td>14.78</td>
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<tr>
<td>Chem mart Roxithromycin [CH]</td>
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<tr>
<td>Roximycin [AF]</td>
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<td></td>
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<tr>
<td>Roxithromycin-GA [ED]</td>
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</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
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**Roxithromycin 150 mg tablet, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
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<tbody>
<tr>
<td>APO-Roxithromycin [TX]</td>
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<td>14.78</td>
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<tr>
<td>Chem mart Roxithromycin [CH]</td>
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<td></td>
</tr>
<tr>
<td>Roximycin [AF]</td>
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</tr>
<tr>
<td>Roxithromycin-GA [ED]</td>
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<tr>
<td>Roxithromycin Sandoz [SZ]</td>
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**Roxithromycin 300 mg tablet, 5**

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<td>14.78</td>
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<td>Chem mart Roxithromycin [CH]</td>
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<td>Roximycin [AF]</td>
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<tr>
<td>Roxithromycin-GA [ED]</td>
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<tr>
<td>Roxithromycin Sandoz [SZ]</td>
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**Roxithromycin 300 mg tablet, 5**

<table>
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<tr>
<td>APO-Roxithromycin [TX]</td>
<td>13.57</td>
<td>14.78</td>
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<td>Chem mart Roxithromycin [CH]</td>
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<td>Roximycin [AF]</td>
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<tr>
<td>Roxithromycin-GA [ED]</td>
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<td>Roxithromycin Sandoz [SZ]</td>
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**Roxithromycin 50 mg dispersible tablet, 10**

<table>
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**Roxithromycin 50 mg dispersible tablet, 10**

<table>
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<td>16.72</td>
<td>17.93</td>
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#### Clindamycin

**Clindamycin 150 mg capsule, 24**

<table>
<thead>
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<td>APO-Clindamycin [TX]</td>
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<td>Chem mart Clindamycin [CH]</td>
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<tr>
<td>Cleocin [FZ]</td>
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</table>
**ANTIINFECTIVES FOR SYSTEMIC USE**

### CLINDAMYCIN

**Restricted benefit**

Gram-positive coccal infections

**Clinical criteria:**
- The condition must not be able to be safely and effectively treated with a penicillin.

**Clindamycin 150 mg capsule, 24**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>Calindamin [RW]</td>
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<tr>
<td>Chem mart Clindamycin [CH]</td>
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<tr>
<td>Clindamycin BNM [BZ]</td>
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<tr>
<td>Clindamycin [AF]</td>
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### LINCOMYCIN

**lincomycin 600 mg/2 mL injection, 5 x 2 mL vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lincocin [PF]</td>
<td>142.86</td>
<td>38.80</td>
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</tbody>
</table>

### AMINOGLYCOSIDE ANTIBACTERIALS

**Other aminoglycosides**

### GENTAMICIN

**gentamicin 80 mg/2 mL ampoules**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>Pfizer Australia Pty Ltd [PF]</td>
<td>22.61</td>
<td>23.82</td>
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</table>

### TOBRAMYCIN

**Restricted benefit**

Pseudomonas aeruginosa infection

**Clinical criteria:**
- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

**tobramycin 500 mg/5 mL injection, 10 x 5 mL vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>Tobra-Day [PL]</td>
<td>279.78</td>
<td>38.80</td>
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### TOBRAMYCIN

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
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<td>Pfizer Australia Pty Ltd [PF]</td>
<td>48.31</td>
<td>38.80</td>
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</tbody>
</table>

**tobramycin 80 mg/2 mL injection, 5 x 2 mL vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>Hospira Pty Limited [PF]</td>
<td>48.31</td>
<td>38.80</td>
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</tbody>
</table>

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

Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

Proven Pseudomonas aeruginosa infection
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

Population criteria:
- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>TOBI podhaler [NV]</td>
<td>1</td>
<td>..</td>
<td>2432.37</td>
<td>38.80</td>
<td></td>
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</table>

**TOBRAMYCIN**

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

Proven Pseudomonas aeruginosa infection
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

Population criteria:
- Patient must be 6 years of age or older.

**tobramycin 28 mg powder for inhalation, 224 capsules**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>TOBI podhaler [NV]</td>
<td>1</td>
<td>2</td>
<td>2432.37</td>
<td>38.80</td>
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</tr>
</tbody>
</table>

**TOBRAMYCIN**

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

Proven Pseudomonas aeruginosa infection
Clinical criteria:
- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>2</td>
<td>1048.47</td>
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</tr>
</tbody>
</table>

**QUINOLONE ANTIBACTERIALS**

**Fluoroquinolones**

**CIPROFLOXACIN**

Authority required
Respiratory tract infection
Clinical criteria:
- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

Authority required
Bacterial gastroenteritis
Clinical criteria:
- Patient must be severely immunocompromised.

Authority required

Infection
Clinical criteria:
- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection
Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis
Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna
Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Respiratory tract infection
Clinical criteria:
- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, AND
- Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis
Clinical criteria:
- Patient must be severely immunocompromised.

Authority required

Infection
Clinical criteria:
- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection
ANTIINFECTIVES FOR SYSTEMIC USE

Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Epididymo-orchitis

Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Prostatitis

Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Perichondritis of the pinna

Clinical criteria:
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

Gonorrhoea

ciprofloxacin 250 mg tablet, 14

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1208N</td>
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<td>14.29</td>
<td>15.50</td>
<td>* APO-Ciprofloxacin [TX]</td>
<td>* C-Flox 250 [AL]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ciprofloxacin Sandoz [SZ]</td>
<td>* Ciprol 250 [RW]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B1.74</td>
<td>16.03</td>
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**NORFLOXACIN**

**Authority required**

Acute bacterial enterocolitis

**Authority required**

Complicated urinary tract infection

norfloxacin 400 mg tablet, 14

<table>
<thead>
<tr>
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<tr>
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<td>14.67</td>
<td>15.88</td>
<td>* GenRx Norfloxacin [GX]</td>
<td>* Nufloxib [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Roxin [RW]</td>
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</tr>
</tbody>
</table>

**OTHER ANTIBACTERIALS**

**Glycopeptide antibacterials**

**VANCOMYCIN**

**Restricted benefit**

Endocarditis

Clinical criteria:
- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>2269K</td>
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<td>15.92</td>
<td>17.13</td>
<td>* Hospira Pty Limited [PF]</td>
<td>* Vancomycin Alphapharm [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Vycin IV [EA]</td>
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</table>

vancomycin 500 mg injection, 1 vial

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3130R</td>
<td>2</td>
<td>..</td>
<td>16.81</td>
<td>18.02</td>
<td>* Hospira Pty Limited [PF]</td>
<td>* Vancomycin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

**VANCOMYCIN**

**Restricted benefit**

Endocarditis

Clinical criteria:
### Antiinfectives for Systemic Use

#### Vancomycin 1 g injection, 1 vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>17.13</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Vancomycin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

**VANCOMYCIN**

- **Restricted benefit**
  - Endophthalmitis
  - Infection

**Clinical criteria:**
- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

#### Vancomycin 500 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>20.72</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vancomycin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

#### Steroid antibacterials

- **FUSIDATE**
  - **Restricted benefit**
  - Serious staphylococcal infections

**Clinical criteria:**
- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

#### Sodium fusidate 250 mg tablet, 36

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>2312Q</td>
<td></td>
<td></td>
<td>84.04</td>
<td>90.72</td>
<td>Fucidin [CS]</td>
</tr>
</tbody>
</table>

#### FUSIDATE

- **Authority required (STREAMLINED)**
  - Osteomyelitis

**Clinical criteria:**
- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

#### Sodium fusidate 250 mg tablet, 36

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>10782L</td>
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<td>41.72</td>
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#### Imidazole derivatives

- **METRONIDAZOLE**
  - Metronidazole 200 mg tablet, 21

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<thead>
<tr>
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<tr>
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<td>13.54</td>
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<tr>
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<td></td>
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<td>Metronide 200 [AV]</td>
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</table>

**Flagyl [SW]**

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<tr>
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<tr>
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<td>13.57</td>
<td>Metrogyl 200 [AF]</td>
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<td></td>
<td></td>
<td>Metronide 200 [AV]</td>
</tr>
</tbody>
</table>
**ANTIINFECTIVES FOR SYSTEMIC USE**

### Metronidazole

**Metronidazole 200 mg/5 mL oral liquid, 100 mL**

<table>
<thead>
<tr>
<th>1630T</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
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<td></td>
<td></td>
<td>21.87</td>
<td>23.08</td>
<td>Flagyl S [SW]</td>
</tr>
</tbody>
</table>

**Metronidazole 200 mg/5 mL oral liquid, 100 mL**

<table>
<thead>
<tr>
<th>3341W</th>
<th>Max Qty Packs</th>
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<td>NP</td>
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<td></td>
<td>21.87</td>
<td>23.08</td>
<td>Flagyl S [SW]</td>
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</table>

**Metronidazole 500 mg suppository, 10**

<table>
<thead>
<tr>
<th>1642K</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>25.65</td>
<td>26.86</td>
<td>Flagyl [SW]</td>
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**Metronidazole 500 mg suppository, 10**

<table>
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<th>DPMQ $</th>
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### Metronidazole

**Restricted benefit**

**Anaerobic infections**

**Metronidazole 400 mg tablet, 21**

<table>
<thead>
<tr>
<th>1621H</th>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
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<td></td>
<td>Metrogyl 400 [AF]</td>
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<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Metronide 400 [AV]</td>
</tr>
</tbody>
</table>

### Metronidazole

**Restricted benefit**

**Acute anaerobic sepsis**

**Treatment criteria:**

- Must be treated in a hospital.

**Metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags**

<table>
<thead>
<tr>
<th>1832K</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td>20.81</td>
<td>22.02</td>
<td>Metronidazole Sandoz IV [SZ]</td>
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</table>

### Metronidazole

**Restricted benefit**

**Anaerobic infections**

**Metronidazole 400 mg tablet, 21**

<table>
<thead>
<tr>
<th>5155H</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td>14.07</td>
<td>15.28</td>
<td>Metrogyl 400 [AF]</td>
</tr>
<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Metronide 400 [AV]</td>
</tr>
<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td>2.00</td>
<td>16.07</td>
<td>Flagyl [SW]</td>
</tr>
</tbody>
</table>

### Metronidazole

**Restricted benefit**

**Prophylaxis to prevent infection**

**Clinical criteria:**

- Patient must be undergoing large bowel surgery.

**Restricted benefit**

**Acute anaerobic sepsis**

**Treatment criteria:**

- Must be treated in a hospital.

**Metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags**

<table>
<thead>
<tr>
<th>1821W</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>NP</td>
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<td></td>
<td></td>
<td>20.81</td>
<td>22.02</td>
<td>Metronidazole Sandoz IV [SZ]</td>
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### Tinidazole

**Tinidazole 500 mg tablet, 4**

<table>
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<td>16.10</td>
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<td>6.70</td>
<td>21.59</td>
<td>Fasigyn [PF]</td>
</tr>
</tbody>
</table>

**Nitrofuran derivatives**
# Antiinfectives for Systemic Use

## Nitrofurantoin

*Caution* Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

<table>
<thead>
<tr>
<th>Nitrofurantoin 100 mg capsule, 30</th>
<th>1693D</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
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<td></td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>32.12</td>
<td>33.33</td>
<td>Macrodantin [PF]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nitrofurantoin 50 mg capsule, 30</th>
<th>1692C</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td></td>
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<td>1</td>
<td>1</td>
<td>..</td>
<td>26.08</td>
<td>27.29</td>
<td>Macrodantin [PF]</td>
</tr>
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</table>

## Hexamine Hippurate

<table>
<thead>
<tr>
<th>Hexammine hippurate 1 g tablet, 100</th>
<th>3124K</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
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<td></td>
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<td>5</td>
<td>..</td>
<td>44.11</td>
<td>38.80</td>
<td>Hiprex [IA]</td>
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</tbody>
</table>

## Antimycotics for Systemic Use

### Triazole Derivatives

## Fluconazole

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

<table>
<thead>
<tr>
<th>Fluconazole 100 mg capsule, 28</th>
<th>1472L</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>31.81</td>
<td>33.02</td>
<td>* Diflucan [PF]</td>
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</table>

<table>
<thead>
<tr>
<th>Fluconazole 100 mg/50 mL injection, 50 mL vial</th>
<th>1473M</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>..</td>
<td>..</td>
<td>21.08</td>
<td>22.29</td>
<td>* Dizole 100 [AF]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fluconazole 400 mg/200 mL injection, 200 mL bag</th>
<th>1757L</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
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<td>1</td>
<td>..</td>
<td>..</td>
<td>15.33</td>
<td>16.54</td>
<td>Fluconazole Alphapharm [AF]</td>
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</table>
**FLUCONAZOLE**

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

### Restricted benefit

**Cryptococcal meningitis**

**Clinical criteria:**
- Patient must be unable to take a solid dose form of fluconazole.

### Restricted benefit

**Oropharyngeal candidiasis**

**Clinical criteria:**
- Patient must be immunosuppressed, AND
- Patient must be unable to take a solid dose form of fluconazole.

### Restricted benefit

**Oesophageal candidiasis**

**Clinical criteria:**
- Patient must be immunosuppressed, AND
- Patient must be unable to take a solid dose form of fluconazole.

### Restricted benefit

**Candida infections**

**Clinical criteria:**
- The condition must be serious or life-threatening, AND
- Patient must be unable to take a solid dose form of fluconazole.

---

**FLUCONAZOLE**

**Note**
Pharmaceutical benefits that have the forms fluconazole 200 mg/100 mL injection, 100 mL vial and fluconazole 200 mg/100 mL injection, 100 mL bag are equivalent for the purposes of substitution.

### Restricted benefit

**Cryptococcal meningitis**

**Clinical criteria:**
- The treatment must be maintenance therapy, AND
- Patient must be immunosuppressed, AND
- Patient must be unable to take a solid dose form of fluconazole.

---

**FLUCONAZOLE**

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

**Note**
Pharmaceutical benefits that have the forms fluconazole 200 mg/100 mL injection, 100 mL vial and fluconazole 200 mg/100 mL injection, 100 mL bag are equivalent for the purposes of substitution.

### Restricted benefit

**Cryptococcal meningitis**

**Clinical criteria:**
- The treatment must be maintenance therapy, AND

---
ANTIINFECTIVES FOR SYSTEMIC USE

- Patient must be immunosuppressed.

**Restricted benefit**

**General**

- Patient must be immunosuppressed.

**Clinical criteria:**

**Restricted benefit**

**Oropharyngeal candidiasis**

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

**Oesophageal candidiasis**

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

**Oropharyngeal candidiasis**

**Clinical criteria:**

- The treatment must be for prophylaxis, AND
- Patient must be immunosuppressed.

**Restricted benefit**

**Candida infections**

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 200 mg/100 mL injection, 100 mL vial**

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**fluconazole 200 mg/100 mL injection, 100 mL bag**

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**ITRACONAZOLE**

**Note**

One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

**Note**

Not for use in superficial mycoses

**Note Shared Care Model:**

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

**Restricted benefit**

**Systemic aspergillosis**

**Restricted benefit**

**Systemic sporotrichosis**

**Restricted benefit**

**Systemic histoplasmosis**

**Restricted benefit**

Disseminated pulmonary histoplasmosis infection

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Restricted benefit**

Chronic pulmonary histoplasmosis infection

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Restricted benefit**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Restricted benefit**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**itraconazole 100 mg capsule, 60**

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ANTIINFECTIVES FOR SYSTEMIC USE

itraconazole 50 mg capsule, 60
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- **POSACONAZOLE**

  **Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

  **Authority required**
  Invasive aspergillosis
  Clinical criteria:
  - Patient must be unable to tolerate alternative therapy; OR
  - Patient must have disease refractory to alternative therapy.

  **Authority required**
  Prophylaxis of invasive fungal infections including both yeasts and moulds
  Clinical criteria:
  - Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
  - Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

  Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

  Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

  No more than 6 months therapy per episode will be PBS-subsidised

- **POSACONAZOLE**

  **Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

  **Authority required**
  Invasive aspergillosis
  Clinical criteria:
  - Patient must be unable to tolerate alternative therapy; OR
  - Patient must have disease refractory to alternative therapy.

  **Authority required**
  Fungal infection
  Clinical criteria:
  - The condition must be fusariosis; OR
  - The condition must be zygomycosis; OR
  - The condition must be coccidioidomycosis; OR
  - The condition must be chromoblastomycosis; OR
  - The condition must be mycetoma, **AND**
  - Patient must be unable to tolerate alternative therapy; OR
  - Patient must have disease refractory to alternative therapy.

posaconazole 100 mg modified release tablet, 24
10460M

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- **POSACONAZOLE**

  **Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

  **Authority required**
  Invasive aspergillosis
  Clinical criteria:
  - Patient must be unable to tolerate alternative therapy; OR
  - Patient must have disease refractory to alternative therapy.

  **Authority required**
  Fungal infection
  Clinical criteria:
  - The condition must be fusariosis; OR
  - The condition must be zygomycosis; OR
  - The condition must be coccidioidomycosis; OR
  - The condition must be chromoblastomycosis; OR
  - The condition must be mycetoma, **AND**
  - Patient must be unable to tolerate alternative therapy; OR
  - Patient must have disease refractory to alternative therapy.
ANTIINFECTIVES FOR SYSTEMIC USE

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**
- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

**posaconazole 40 mg/mL oral liquid, 105 mL**

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**VORICONAZOLE**

**Note** For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note** For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

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

**Authority required**
Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**
- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

**voriconazole 50 mg tablet, 56**

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**voriconazole 200 mg tablet, 56**

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**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

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**VORICONAZOLE**

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

**Authority required**
Definite or probable invasive aspergillosis

**Treatment Phase:** Treatment and maintenance therapy

**Clinical criteria:**
- Patient must be immunocompromised.

**Authority required**
Serious fungal infections

**Treatment Phase:** Treatment and maintenance therapy

**Clinical criteria:**
- The condition must be caused by Scedosporium species; OR
- The condition must be caused by Fusarium species.
ANTIINFECTIVES FOR SYSTEMIC USE

General Pharmaceutical Benefits

Authority required
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
• The condition must be caused by species not susceptible to fluconazole; OR
• The condition must be resistant to fluconazole; OR
• Patient must be unable to tolerate fluconazole.

Authority required
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
• The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

Voriconazole 50 mg tablet, 56

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Voriconazole 200 mg tablet, 56

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VORICONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

Authority required
Definite or probable invasive aspergillosis
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
• Patient must be immunocompromised.

Authority required
Serious fungal infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
• The condition must be caused by Scedosporium species; OR
• The condition must be caused by Fusarium species.

Authority required
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
• The condition must be caused by species not susceptible to fluconazole; OR
• The condition must be resistant to fluconazole; OR
• Patient must be unable to tolerate fluconazole.

Authority required
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:
• The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

Voriconazole 40 mg/mL powder for oral liquid, 70 mL

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ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Hydrazides

ISONIAZID

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical
Antiinfectives for Systemic Use

**General practitioner** in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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### Drugs for Treatment of Lepra

**Drugs for treatment of lepra**

**Dapsone**

Note Shared Care Model:

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

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### Rifampicin

Note Shared Care Model:

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

**Authority required**

Leprosy

Population criteria:
- Patient must be an adult.

**Rifampicin 150 mg capsule, 100**

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**Rifampicin 300 mg capsule, 100**

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**Rifampicin 150 mg capsule, 10**

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### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

### ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

#### Authority required (STREAMLINED)

**5942**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

#### aciclovir 200 mg tablet, 90

**1007B**

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* Aciclovir 200 [CR]
* Aciclovir AN [ED]
* Aciclovir GH [GQ]
* Acyclovir 200 [AF]
* GenRx Aciclovir [GX]
* Lovir [EA]
* Ozvir [RA]

*0.91 36.54 36.84 Zovirax 200 mg [GK]

### ACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

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

#### Authority required (STREAMLINED)

**5967**

Herpes zoster

Clinical criteria:
- The treatment must be administered within 72 hours of the onset of the rash.

#### aciclovir 800 mg tablet, 35

**1052J**

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* Aciclovir 800 [CR]
* GenRx Aciclovir [GX]
* Aciclovir Sandoz [HX]

### ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

#### Authority required (STREAMLINED)

**5936**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

#### aciclovir 200 mg tablet, 25

**1003T**

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* Aciclovir Sandoz [HX]

#### aciclovir 200 mg tablet, 50

**1555W**

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* GenRx Aciclovir [GX]
### FAMCICLOVIR

**Note** Famiciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

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**FAMCICLOVIR**

**Note** Famiciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Note** Famiciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

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**FAMCICLOVIR**

**Note** Famiciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

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**FAMCICLOVIR**

**Note** Famiciclovir 250 mg is not PBS-subsidised for chickenpox.

**Authority required (STREAMLINED)**

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**FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famiciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

**Authority required (STREAMLINED)**

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**FAMCICLOVIR**

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famiciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famiciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.
ANTIINFECTIVES FOR SYSTEMIC USE

General Pharmaceutical Benefits 233

Note No applications for repeats will be authorised.

Authority required (STREAMLINED) 5943
Herpes zoster
Clinical criteria:
• Patient must be immunocompromised, AND
• The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 500 mg tablet, 30

8897G

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
-----|-----|-----|-----|-----|-----|-----
1 | .. | .. | 43.69 | 38.80 | APO-Famciclovir [TX] | Auro-Famciclovir 500 [DO]

FAMCICLOVIR

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.
Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Authority required (STREAMLINED) 5954
Recurrent moderate to severe genital herpes
Treatment Phase: Episodic treatment or suppressive therapy
Clinical criteria:
• Patient must be immunocompromised.
Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED) 5947
Recurrent moderate to severe oral or labial herpes
Treatment Phase: Episodic treatment
Clinical criteria:
• Patient must have HIV infection, AND
• Patient must have CD4 cell count of less than 500 million per litre.
Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED) 5948
Recurrent moderate to severe oral or labial herpes
Treatment Phase: Suppressive therapy
Clinical criteria:
• Patient must have HIV infection, AND
• Patient must have CD4 cell counts of less than 150 million per litre.
Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED) 5949
Recurrent moderate to severe oral or labial herpes
Treatment Phase: Suppressive therapy
Clinical criteria:
• Patient must have HIV infection, AND
• Patient must present with other opportunistic infections or AIDS defining tumours.
Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 500 mg tablet, 56

8896F

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
-----|-----|-----|-----|-----|-----|-----
1 | 5 | .. | 71.95 | 38.80 | APO-Famciclovir [TX] | Auro-Famciclovir 500 [DO]

RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.
ANTIINFECTIVES FOR SYSTEMIC USE

**Authority required**
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**RIBAVIRIN**

**Caution**
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

**Authority required**
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**RIBAVIRIN**

** valsaciclovir 500 mg tablet, 30**

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**Authority required (STREAMLINED)**
5940

**Recurrent moderate to severe genital herpes**

**Treatment Phase: Suppressive therapy**

Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)) is desirable but need not delay treatment.

**VALACICLOVIR**

**Note**
Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
ANTIINFECTIVES FOR SYSTEMIC USE

General Pharmaceutical Benefits  235

**VALACICLOVIR**

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

| Authority required (STREAMLINED)  
| 5961  
| Recurrent moderate to severe genital herpes  
| Treatment Phase: Episodic treatment  
| Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.  

valaciclovir 500 mg tablet, 30

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**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

| Authority required (STREAMLINED)  
| 5960  
| Initial moderate to severe genital herpes  
| Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.  

valaciclovir 500 mg tablet, 10

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**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

| Authority required (STREAMLINED)  
| 5962  
| Initial moderate to severe genital herpes  
| Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.  

valaciclovir 500 mg tablet, 42

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**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

| Authority required (STREAMLINED)  
| 5968  
| Initial moderate to severe genital herpes  
| Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.  

**Other antivirals**

**DACLATASVIR**

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

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

**Note** Special Pricing Arrangements apply.
ANTIINFECTIVES FOR SYSTEMIC USE

Authority required
Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 12 weeks.

### DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 24 weeks.

### GRAZOPREVIR + ELBASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 16 weeks.

### GRAZOPREVIR + ELBASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
ANTIINFECTIVES FOR SYSTEMIC USE

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

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### LEDIPASVIR + SOFOSBUVIR

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

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

**Note** Special Pricing Arrangements apply.

- **Authority required**
  - Chronic hepatitis C infection
- **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

<table>
<thead>
<tr>
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<th>MRVS $</th>
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<td>22216.19</td>
<td>38.80</td>
<td>Harvoni [GI]</td>
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### LEDIPASVIR + SOFOSBUVIR

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

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

**Note** Special Pricing Arrangements apply.

- **Authority required**
  - Chronic hepatitis C infection
- **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

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<td>Harvoni [GI]</td>
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### LEDIPASVIR + SOFOSBUVIR

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

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

**Note** Special Pricing Arrangements apply.

- **Authority required**
  - Chronic hepatitis C infection
- **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

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<td>Harvoni [GI]</td>
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### PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

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

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

**Note** Special Pricing Arrangements apply.

- **Authority required**
  - Chronic hepatitis C infection
- **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 12 weeks.
### Paritaprevir + Ritonavir + Ombitasvir & Dasabuvir & Ribavirin

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**
- Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Authority required**
- Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

## Schedule of Pharmaceutical Benefits – November 2017

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**Sofosbuvir**

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

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

**Note** Special Pricing Arrangements apply.
• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg tablet, 28

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**SOFOSBUVIR**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 24 weeks.

sofosbuvir 400 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**SOFOSBUVIR + VELPATASVIR**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

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**VACCINES**

**BACTERIAL VACCINES**

**Pneumococcal vaccines**

**PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES**

**Restricted benefit**

Prophylaxis of pneumococcal infection

**Clinical criteria:**

• Patient must have undergone a splenectomy.

**Population criteria:**

• Patient must be aged 2 years or older.

**Restricted benefit**

Prophylaxis of pneumococcal infection

**Clinical criteria:**

• Patient must have Hodgkin's disease; OR
• Patient must have a high risk of contracting pneumococcal infections.

pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL syringe

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pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL vial

<table>
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<td>38.80</td>
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<td>Pneumovax 23 [CS]</td>
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</table>
Tetanus vaccines

**DIPHTHERIA TOXOID + TETANUS TOXOID**

Note For immunisation of adults and children aged greater than or equal to 8 years.

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

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

<table>
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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**ALKYLATING AGENTS**

**Nitrogen mustard analogues**

**CHLORAMBUCIL**

chlorambucil 2 mg tablet, 25

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**CYCLOPHOSPHAMIDE**

cyclophosphamide 50 mg tablet, 50

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cyclophosphamide 50 mg tablet, 50

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**MELPHALAN**

melphalan 2 mg tablet, 25

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**Alkyl sulfonates**

**BUSULFAN**

busulfan 2 mg tablet, 100

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**Nitrosoureas**

**CARMUSTINE**

Note Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

Restricted benefit
Glioblastoma multiforme

Clinical criteria:
- The condition must be suspected or confirmed at the time of initial surgery.

carmustine 7.7 mg implant, 8

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Other alkylating agents
### TEMOZOLOMIDE

#### temozolomide 5 mg capsule, 5

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<td>* Temozolomide Alphapharm [AF]</td>
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#### temozolomide 100 mg capsule, 5

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#### temozolomide 180 mg capsule, 5

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#### temozolomide 20 mg capsule, 5

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#### temozolomide 140 mg capsule, 5

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<td>* Temozolomide Amneal [ED]</td>
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### TEMOZOLOMIDE

- **Note**: Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.
- **Note**: No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Glioblastoma multiforme

**Treatment criteria:**

- Patient must be undergoing concomitant radiotherapy.

---

**temozolomide 5 mg capsule, 5**

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<td>* Orion Temozolomide [ON]</td>
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<td></td>
<td></td>
<td>* Temizole 5 [QA]</td>
<td>* Temodal [MK]</td>
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<td></td>
<td></td>
<td>* Temolide [JU]</td>
<td>* Temozolomide Amneal [ED]</td>
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**temozolomide 100 mg capsule, 5**

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<td>* Temodal [MK]</td>
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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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<th>Temozolomide 140 mg capsule, 5</th>
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<tr>
<td>9361Q</td>
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</tbody>
</table>

**ANTIMETABOLITES**

**Folic acid analogues**

### METHOTREXATE

**methotrexate 2.5 mg tablet, 30**

| 1622J | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 5 | .. | 16.92 | 18.13 | Methoblastin [PF] |

**methotrexate 5 mg/2 mL injection, 5 x 2 mL vials**

| 2396D | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | .. | 28.79 | 30.00 | Hospira Pty Limited [PF] |

**methotrexate 10 mg tablet, 15**

| 2272N | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 3 | .. | 23.19 | 24.40 | Methoblastin [PF] |

### METHOTREXATE

**Restricted benefit**

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

| 1623K | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 51.41 | 38.80 | Methoblastin [PF] |

### METHOTREXATE

**Note** For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

**METHOTREXATE Injection 50 mg in 2 mL, 1**

| 1818Q | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 5 | 5 | .. | *27.95 | 29.16 | * Methotrexate Accord [OD] |

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

| 2395C | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 5 | .. | 27.92 | 29.13 | * Hospira Pty Limited [PF] |

**Purine analogues**

### FLUDARABINE

**fludarabine phosphate 10 mg tablet, 20**

| 9184J | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 5 | .. | 930.60 | 38.80 | Fludara [GZ] |
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

### MERCAPTOPURINE

**mercaptopurine 50 mg tablet, 25**

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<th>Premium $</th>
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**mercaptopurine 20 mg/mL oral liquid, 100 mL**

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### THIOGUANINE

**thioguanine 40 mg tablet, 25**

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**Pyrimidine analogues**

### CAPECITABINE

**capecitabine 150 mg tablet, 60**

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<td>27.29</td>
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<td>* Capecitabine MYX [OC]</td>
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<td></td>
<td>* Xelocitabine [JU]</td>
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**capecitabine 500 mg tablet, 120**

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<td>* Capecitabine Apotex [TX]</td>
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<td></td>
<td>* Xelocitabine [JU]</td>
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### PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

**Vinc a alkaloids and analogues**

### VINORELBINE

Authority required

Advanced breast cancer

Clinical criteria:
- Patient must have failed standard prior therapy, which includes an anthracycline.

**vinorelbine 20 mg capsule, 1**

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<thead>
<tr>
<th>Max Qty Packs</th>
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**vinorelbine 30 mg capsule, 1**

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<td>9010F</td>
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<td>1878.83</td>
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Podophyllotoxin derivatives

### ETOPOSIDE

**etoposide 100 mg capsule, 10**

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<td>383.92</td>
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**etoposide 50 mg capsule, 20**

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<td>440.03</td>
<td>38.80</td>
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### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

**Anthracyclines and related substances**

### IDARUBICIN

Restricted benefit
Acute myelogenous leukaemia (AML)

idarubicin hydrochloride 5 mg capsule, 1

<table>
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<tr>
<th>2446R</th>
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<th>No. of Rpts</th>
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<td>*306.61</td>
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<td>Zavedos [PF]</td>
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idarubicin hydrochloride 10 mg capsule, 1

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<td>...</td>
<td>*490.51</td>
<td>38.80</td>
<td>Zavedos [PF]</td>
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OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

RITUXIMAB

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

Authority required (STREAMLINED)

6011

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, AND
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, AND
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

<table>
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<th>10709P</th>
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<td>7</td>
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<td>2853.30</td>
<td>38.80</td>
<td>Mabthera SC [RO]</td>
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</tbody>
</table>

RITUXIMAB

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

Authority required (STREAMLINED)

5998

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

- The treatment must be for re-induction treatment purposes only, AND
- The condition must have relapsed or be refractory to treatment, AND
- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

Authority required (STREAMLINED)

6039

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

- The treatment must be for re-induction treatment purposes only, AND
- The condition must have relapsed or be refractory to treatment, AND
- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

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<td>2853.30</td>
<td>38.80</td>
<td>Mabthera SC [RO]</td>
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</table>

RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

Authority required (STREAMLINED)

6161

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:
• Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, AND
• Patient must not have received bendamustine induction therapy, AND
• The treatment must be maintenance therapy, AND
• Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>2853.30</td>
<td>38.80</td>
<td>Mabthera SC [RO]</td>
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</table>

### RITUXIMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

**Authority required (STREAMLINED)**

**6309**
Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma
Treatment Phase: Induction treatment
Clinical criteria:
• The treatment must be in combination with PBS-subsidised chemotherapy, AND
• The condition must be previously untreated, AND
• The treatment must be for induction treatment purposes only, AND
• Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.
An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

**Authority required (STREAMLINED)**

**6162**
Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy
Treatment Phase: Induction treatment
Clinical criteria:
• The treatment must be in combination with PBS-subsidised chemotherapy, AND
• The condition must be previously untreated, AND
• The condition must be symptomatic, AND
• The treatment must be for induction treatment purposes only, AND
• Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.
An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

### TRASTUZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Locally advanced HER2 positive breast cancer
Treatment Phase: Continuing treatment (3 weekly regimen)
Clinical criteria:
• Patient must have previously received treatment with PBS-subsidised trastuzumab, AND
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND
• Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.
Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required
Early HER2 positive breast cancer
Treatment Phase: Continuing treatment (3 weekly regimen)
Clinical criteria:
• Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
• Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.
Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

trastuzumab 600 mg/5 mL injection, 5 mL vial

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>2945.37</td>
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**TRASTUZUMAB**

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Locally advanced HER2 positive breast cancer
Treatment Phase: Initial treatment (3 weekly regimen)
Clinical criteria:
• Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
• Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
HER2 positivity must be demonstrated by in situ hybridisation (ISH).
Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:
(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
(ii) a copy of the signed patient acknowledgement form.
Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required
Early HER2 positive breast cancer
Treatment Phase: Initial treatment (3 weekly regimen)
Clinical criteria:
• Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
• Patient must have undergone surgery, **AND**
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
• Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
HER2 positivity must be demonstrated by in situ hybridisation (ISH).
Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:
(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
(ii) a copy of the signed patient acknowledgement form.
Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

trastuzumab 600 mg/5 mL injection, 5 mL vial

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<th>Max Qty Packs</th>
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<th>Premium</th>
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<th>MRVSN</th>
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<tr>
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<td>..</td>
<td>2945.37</td>
<td>38.80</td>
<td>Herceptin SC [RO]</td>
</tr>
</tbody>
</table>
- **TRASTUZUMAB**
  
  **Note** No applications for increased maximum quantities will be authorised.
  
  **Note** No applications for increased repeats will be authorised.
  
  **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
  
  Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
  
  Applications for authority to prescribe should be forwarded to:
  
  Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001
  
  **Note** Special Pricing Arrangements apply.
  
  **Authority required**
  
  Metastatic (Stage IV) HER2 positive breast cancer
  
  **Treatment Phase: Initial treatment**
  
  **Clinical criteria:**
  
  - Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
  - The treatment must not be in combination with nab-paclitaxel, **AND**
  - The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.
  
  Authority applications for initial treatment must be made in writing and must include:
  
  (a) a completed authority prescription form; and
  
  (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the patient has Stage IV disease.
  
  Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.
  
  **trastuzumab 600 mg/5 mL injection, 5 mL vial**
  
  10798H
  
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  **TRASTUZUMAB**
  
  **Note** No applications for increased maximum quantities will be authorised.
  
  **Note** No applications for increased repeats will be authorised.
  
  **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
  
  Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, authority approval will be granted for a new loading dose.
  
  Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.
  
  **trastuzumab 600 mg/5 mL injection, 5 mL vial**
  
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  **TRASTUZUMAB**
  
  **Note** No applications for increased maximum quantities will be authorised.
  
  **Note** No applications for increased repeats will be authorised.
  
  **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
  
  **Note** Special Pricing Arrangements apply.
  
  **Authority required**
  
  HER2 positive breast cancer
  
  **Treatment Phase: Grandfathering treatment**
  
  **Clinical criteria:**
• Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, AND
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

trastuzumab 600 mg/5 mL injection, 5 mL vial

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**Protein kinase inhibitors**

▪ **AXITINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**
• Patient must have previously been issued with an authority prescription for this drug for this condition, AND
• Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

axitinib 1 mg tablet, 28

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▪ **AXITINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, AND
• Patient must have a WHO performance status of 2 or less, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

axitinib 1 mg tablet, 28

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**CERITINIB**

- **Note**: No increase in the maximum number of repeats may be authorised.
- **Note**: No increase in the maximum number of units may be authorised.
- **Note**: Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 February 2017, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

ceritinib 150 mg capsule, 3 x 50
11056X

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**COBIMETINIB**

- **Note**: No increase in the maximum number of repeats may be authorised.
- **Note**: No increase in the maximum quantity or number of units may be authorised.
- **Note**: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

6839
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must not have progressive disease when treated with a BRAF inhibitor.

cobimetinib 20 mg tablet, 63
11074W

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**COBIMETINIB**

- **Note**: A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
- **Note**: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

6803
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**COBIMETINIB 20 mg tablet, 63**

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**CRIZOTINIB**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment

Clinical criteria:
- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

Note: Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**CRIZOTINIB**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Special Pricing Arrangements apply.

**DABRAFENIB**

Note: A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

6044
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment
Clinical criteria:
- The condition must be positive for a BRAF V600 mutation, AND
- The condition must not have been treated previously with PBS subsidised therapy; OR
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, AND
- Patient must have a WHO performance status of 2 or less.

dabrafenib 75 mg capsule, 120

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dabrafenib 50 mg capsule, 120

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- **DABRAFENIB**
  - Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
  - Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.
  - Note No increase in the maximum quantity or number of units may be authorised.
  - Note No increase in the maximum number of repeats may be authorised.
  - Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6013
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must have stable or responding disease.

dabrafenib 75 mg capsule, 120

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- **DASATINIB**
  - Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.
  - Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
  - 1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond
  - 2. Continuing First-line treatment
  - Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.
  - First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
  - Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
  - During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
  - 3. Authority approval requirements.Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib. For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using...
the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be a primary diagnosis, AND
- The condition must be in the chronic phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, AND
- The treatment must be for first line therapy for this condition, AND
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and
(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
(4) a signed patient acknowledgement form

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

Clinical criteria:

- The condition must be in the chronic phase, AND
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
- Patient must have demonstrated a major cytogenic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, AND
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) demonstration of continued response to treatment as evidenced by either: (a) a major cytogenetic response [see Note explaining requirements]; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment
Clinical criteria:
- The condition must be in the chronic phase, AND
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, AND
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

dasatinib 50 mg tablet, 60

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**DASATINIB**

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment. Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent. Nilotinib is not approved for patients in blast crisis. 1. Initial second line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period, as long as only one second-line therapy is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response. 2. Initial third line treatment Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent. From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis. 3. Continuing treatment for second and third line treatment All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows: (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent. 4. Authority approval requirements Response criteria to initial treatment with dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Initial treatment
Clinical criteria:
• Patient must not have failed PBS-subsidised first line treatment with this drug for this condition, AND
• Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
• Patient must have failed an adequate trial of PBS-subsidised first line treatment with nilotinib for this condition; OR
• Patient must have experienced intolerance, not a failure of response, to PBS-subsidised second line treatment with
nilotinib for this condition, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or nilotinib is defined as:(i) Lack of response to initial imatinib or nilotinib therapy,
dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL
level of less than 1% within 18 months and thereafter at 12 monthly intervals; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35%
Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR(iii) Loss of a previously
demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by
at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy;
OR(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase
of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood
or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the
peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral
basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the
left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size
below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single
Philadelphia chromosome); OR(i) Blast crisis is defined as either:(1) Percentage of blasts in the peripheral blood or bone
marrow greater than or equal to 30%; or(2) Extramedullary involvement other than spleen and liver; OR(v) Disease
progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils
or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid
leukaemia. Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is
dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL
level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a
completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and(c) a signed patient
acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid
leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL
transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided);
and(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s)
from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or
extramedullary involvement

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have received initial PBS-subsidised second line treatment with this drug for this condition; OR
• Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second line treatment with
nilotinib for this condition, AND
• Patient must have demonstrated a major cytogenetic response in the preceding 18 months and thereafter at 12 monthly
intervals; OR
• Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and
thereafter at 12 monthly intervals, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authority to prescribe must be in writing and must include:(1) a completed authority prescription form; and(2) a
completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and(3)
demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note
explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial
supply), only the date of the relevant pathology report need be provided; or (b) a peripheral blood level of BCR-ABL of
less than 1% on the international scale on the international scale [see Note explaining definitions of response]. Where this has
been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided.

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**DASATINIB**

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

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

**Authority required**

Acute lymphoblastic leukaemia

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation. Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Acute lymphoblastic leukaemia

**Treatment Phase:** Initial Treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have been treated for this condition prior to 1 December 2007, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
• Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.
Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Acute lymphoblastic leukaemia

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
• The condition must be expressing the Philadelphia chromosome; OR
• The condition must have the transcript BCR-ABL, **AND**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• The condition must not have progressed, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**ERLOTINIB**

**Authority required**
Stage IIIb (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
• The treatment must be as monotherapy, **AND**
• Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
• Patient must not have progressive disease.

**Population criteria:**
• Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
• Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

**erlotinib 100 mg tablet, 30**

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**ERLOTINIB**

**Authority required**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- The condition must be squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); **OR**
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

**Population criteria:**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**EVEROLIMUS**

**Note** Special Pricing Arrangements apply.

**Authority required**
Tuberous sclerosis complex (TSC)

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**
Tuberous sclerosis complex (TSC)

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
• Patient must have demonstrated a response to prior treatment.

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### EVEROLIMUS

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**Authority required**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

**Population criteria:**
- Patient must not be pre-menopausal.

**Note**

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**everolimus 5 mg tablet, 30**

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### EVEROLIMUS

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

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**EVEROLIMUS**

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

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

**Note** Special Pricing Arrangements apply.

---

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

---

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient’s medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

---

**EVEROLIMUS**

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

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

**Note** Special Pricing Arrangements apply.

---

**Authority required**

Stage IIIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR

Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, AND

Patient must have a WHO performance status of 2 or less.

Population criteria:

Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have progressive disease.

gefitinib 250 mg tablet, 30

8769M

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IMATINIB

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No applications for increased repeats will be authorised.

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

The condition must be metastatic; OR

The condition must be unresectable, AND

The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, AND

The treatment must be commenced at a dose not exceeding 400 mg per day, AND

The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and

(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be metastatic; OR

The condition must be unresectable, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to...
400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for continuing treatment may be made by telephone.

**Note** For the following diseases, written authority is required at initiation and for continuation:
- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

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### IMATINIB

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Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

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

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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**Authority required**

Myelodysplastic or myeloproliferative disorder

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and
- (d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and
- (e) details of the prior therapy trialled and the response; and
- (f) a signed patient acknowledgement

**Authority required**

Myelodysplastic or myeloproliferative disorder

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response; and
(d) a statement that the disease has not progressed on imatinib therapy

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

No applications for increased repeats will be authorised.

Note

Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

**Chronic eosinophilic leukaemia or Hypereosinophilic syndrome**

**Treatment Phase: Initial treatment**

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) a signed patient acknowledgement

**Authority required**

**Chronic eosinophilic leukaemia or Hypereosinophilic syndrome**

**Treatment Phase: Continuing treatment**

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
(d) a statement that the disease has not progressed on imatinib therapy

**Imatinib 100 mg tablet, 60**

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Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**

No applications for increased repeats will be authorised.

**Note**

Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note**

Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

---

**Authority required**

Dermatofibrosarcoma protuberans

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, AND
- The treatment must not exceed a maximum dose of 800 mg per day.

1. Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and
2. Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and
3. Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a signed patient acknowledgement

**Authority required**

Dermatofibrosarcoma protuberans

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated a response to the PBS-subsidised treatment, AND
• The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
• The treatment must not exceed a maximum dose of 800 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a statement that the disease has not progressed on imatinib therapy.

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**IMATINIB**

**Authority required**
Gastrointestinal stromal tumour
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), AND
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, AND
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, AND
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

Applications for authorisation of initial treatment must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:
   i. a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
   ii. a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.

High risk of recurrence is defined as:
- Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or
- Primary GIST greater than 10 cm with any mitotic rate; or
- Primary GIST with a mitotic count of greater than 10/50 HPF.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.

**Authority required**
Gastrointestinal stromal tumour
Treatment Phase: Continuing treatment

Clinical criteria:
- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), AND
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, AND
The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), AND

Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

Applications for continuing therapy may be made by telephone.

**Note** Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### IMATINIB

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, AND
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, AND
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) details of prior treatment trialled and the response; and
(g) a signed patient acknowledgement

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

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, AND
- Patient must must have achieved and maintained a complete haematological response, AND
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response; and
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(d) a statement that the disease has not progressed on imatinib therapy

Note No applications for increased repeats will be authorised.

imatinib 100 mg tablet, 60

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### IMATINIB

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment. Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Philadelphia positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required
Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have a primary diagnosis of chronic myeloid leukaemia, AND
- The condition must be in the chronic phase of chronic myeloid leukaemia, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, AND
- The treatment must be for first line therapy for this condition, AND
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include:
1. A completed authority prescription form;
2. A completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form;
3. A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
4. A signed patient acknowledgement form.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

Clinical criteria:
- The condition must be in the chronic phase of chronic myeloid leukaemia, AND
- Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
- Patient must have demonstrated a major cytogenic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, AND
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:
1. A completed authority prescription form; and
2. A response to treatment as evidenced by either:
   a) a major cytogenetic response [see Note explaining requirements]; or
   b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Clinical criteria:
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response; **OR**
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Second and subsequent authority applications for continuing therapy with imatinib mesilate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Reply Paid 9826
HOBART TAS 7001

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**IMATINIB**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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**Authority required**

**Chronic Myeloid Leukaemia (CML)**

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

**Authority required**

Chronic Myeloid Leukaemia (CML)
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase.

Blast crisis is defined as either:
1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement.

**Authority required**

Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase.

**Authority required**

Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase.

**imatinib 100 mg tablet, 60**

**imatinib 400 mg tablet, 30**

**imatinib 100 mg capsule, 60**
**IMATINIB**

- **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
- Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

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

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority required**

- **Acute lymphoblastic leukaemia**
  - Treatment Phase: Initial treatment
  - **Clinical criteria:**
    - Patient must be newly diagnosed, **AND**
    - The condition must be expressing the Philadelphia chromosome; **OR**
    - The condition must have the transcript BCR-ABL, **AND**
    - **Clinical criteria:**
      - The treatment must be for induction and consolidation therapy, **AND**
      - The treatment must be in combination with chemotherapy.
  - The authority application must be made in writing and must include:
    - (a) a completed authority prescription form; and
    - (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
    - (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow.
    - (The date of the relevant pathology report needs to be provided); and
    - (d) a signed patient acknowledgement

**Authority required**

- **Acute lymphoblastic leukaemia**
  - Treatment Phase: Initial treatment
  - **Clinical criteria:**
    - The condition must be expressing the Philadelphia chromosome; **OR**
    - The condition must have the transcript BCR-ABL, **AND**
    - Patient must have previously received treatment with this drug for this condition under Imatinib Compassionate Program.
  - The authority application must be made in writing and must include:
    - (a) a completed authority prescription form; and
    - (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
    - (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow.
    - (The date of the relevant pathology report needs to be provided); and
    - (d) a signed patient acknowledgement

**Authority required**

- **Acute lymphoblastic leukaemia**
  - Treatment Phase: Continuing treatment
  - **Clinical criteria:**
    - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
    - The condition must be expressing the Philadelphia chromosome; **OR**
    - The condition must have the transcript BCR-ABL, **AND**
    - **Clinical criteria:**
      - The treatment must be for maintenance of first complete remission, **AND**
      - The treatment must be in combination with chemotherapy.
  - Imatinib is available with a lifetime maximum of 24 months for continuing treatment with imatinib therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.
Note Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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### imatinib 400 mg capsule, 30

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### LAPATINIB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; OR
- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must have progressed following treatment with pertuzumab and trastuzumab in combination, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:
  - (i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;
  - (ii) date of last treatment with a taxane and total number of cycles;
  - (iii) a copy of the signed patient acknowledgement form;
  - (iv) dates of treatment with trastuzumab and pertuzumab; and
  - (v) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

**Treatment Phase:** Continuing treatment
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- The treatment must be in combination with capecitabine, AND
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
The treatment must not exceed a lifetime total of one continuous course.

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

Lapatinib 250 mg tablet, 70

9148L

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LENVATINIB

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

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

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6604
Locally advanced or metastatic differentiated thyroid cancer
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be refractory to radioactive iodine, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, AND
- Patient must have thyroid stimulating hormone adequately repressed, AND
- Patient must be one in whom surgery is inappropriate, AND
- Patient must not be a candidate for radiotherapy with curative intent, AND
- Patient must have a WHO performance status of 2 or less.
Radioactive iodine refractory is defined as:
- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

Authority required (STREAMLINED)

6578
Locally advanced or metastatic differentiated thyroid cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be refractory to radioactive iodine, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

Note: Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

Authority required (STREAMLINED)

6577
Locally advanced or metastatic differentiated thyroid cancer
Treatment Phase: Grandfathering treatment

Clinical criteria:
- The condition must be refractory to radioactive iodine, AND
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, AND
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have thyroid stimulating hormone adequately repressed.

Lenvatinib 4 mg capsule, 30

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Lenvatinib 10 mg capsule, 30

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### NILOTINIB

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved. Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patient identification and eligibility. Switching must be reviewed and therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and (4) a signed patient acknowledgement form.

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alpha therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. **Initial First-line treatment**
   - From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond. 2. **Continuing First-line treatment**
   - Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. **Authority approval requirements**
   - Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib.
(patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

<table>
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<td>Chronic Myeloid Leukaemia (CML)</td>
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<tr>
<td>Treatment Phase: First continuing treatment</td>
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<td>Clinical criteria:</td>
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<tr>
<td>- The condition must be in the chronic phase, AND</td>
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<td>- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR</td>
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<tr>
<td>- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR</td>
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<tr>
<td>- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, AND</td>
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<tr>
<td>- Patient must have demonstrated a major cytogenic response; OR</td>
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<tr>
<td>- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, AND</td>
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<tr>
<td>- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND</td>
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<tr>
<td>- The treatment must be the sole PBS-subsidised therapy for this condition.</td>
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First continuing applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) demonstration of continued response to treatment as evidenced by either: (a) a major cytogenetic response [see Note explaining requirements]; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

<table>
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<td>Chronic Myeloid Leukaemia (CML)</td>
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<tr>
<td>Treatment Phase: Subsequent continuing treatment</td>
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<td>- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR</td>
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<td>- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR</td>
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<td>- Patient must have maintained a major cytogenic response; OR</td>
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</tr>
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<td>- The treatment must be the sole PBS-subsidised therapy for this condition.</td>
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Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120

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NILOTINIB

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, AND
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with dasatinib for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:(i) Lack of response to initial imatinib or dasatinib therapy, defined as either: - failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib; or- failure to achieve a cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test); during ongoing imatinib or dasatinib therapy; OR(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Note: The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment. Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent. Nilotinib is not approved for patients in blast crisis.1. Initial second line treatmentFrom 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.2. Initial third line treatmentThird-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent. From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.3. Continuing treatment for second and third line treatmentAll continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.4. Authority approval requirements. Response criteria to initial treatment with dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the
General

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must have demonstrated a major cytogenetic response to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals; OR
• Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and (3) demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120

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

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

Note Special Pricing Arrangements apply.

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:
• The condition must be diagnosed through a multidisciplinary team, AND
• Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, AND
• Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, AND
• Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, AND
• Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, AND
• Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, AND
• The treatment must be the sole PBS-subsidised treatment for this condition.

Treatment criteria:
• Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician. A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must not have an acute respiratory infection at the time of FVC testing.

Applications for authorisation of initial treatment must be in writing and must include:
• a) a completed authority prescription form; and
• b) a completed IPF Authority Application Supporting Information Form; and
• c) a signed patient acknowledgement.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services

Complex Drugs
**Authority required**

Idiopathic pulmonary fibrosis

**Treatment Phase: Initial treatment 2 - change or re-commencement of treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Idiopathic pulmonary fibrosis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

**Treatment criteria:**
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Idiopathic pulmonary fibrosis

**Treatment Phase: Initial treatment 3 - Grandfathering treatment**

**Treatment criteria:**
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Clinical criteria:**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2017, **AND**
- The condition must have been diagnosed through a multidisciplinary team, **AND**
- Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Patient must have not have an acute respiratory infection at the time of FVC testing.

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

Applications for authorisation of initial treatment must be in writing and must include:
- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

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**nintedanib 150 mg capsule, 60**

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## PAZOPANIB

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

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

**Note** Special Pricing Arrangements apply.

### Authority required

**Advanced (unresectable and/or metastatic) soft tissue sarcoma**

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:
- adipocytic soft tissue sarcoma;
- gastrointestinal stromal tumour (GIST);
- rhabdomyosarcoma other than alveolar or pleomorphic;
- chondrosarcoma;
- osteosarcoma;
- Ewings tumour/primitive neuroectodermal tumour;
- dermatofibromatosis sarcoma protuberans;
- inflammatory myofibroblastic sarcoma;
- malignant mesothelioma;
- mixed mesodermal tumour of the uterus.

The authority application must be made in writing.

### pazopanib 200 mg tablet, 90

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## PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

### Authority required

**Advanced (unresectable and/or metastatic) soft tissue sarcoma**

**Treatment Phase:** Continuing treatment beyond 3 months

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

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PAZOPANIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**
- Advanced (unresectable and/or metastatic) soft tissue sarcoma
- Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

**pazopanib 200 mg tablet, 30**

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PAZOPANIB

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note** Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

**Note** Special Pricing Arrangements apply.

**Authority required**
- Stage IV clear cell variant renal cell carcinoma (RCC)
- Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**pazopanib 200 mg tablet, 30**

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PAZOPANIB

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Authority required**
- Stage IV clear cell variant renal cell carcinoma (RCC)
- Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**
• Patient must have a WHO performance status of 2 or less, **AND**
• The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

### PAZOPANIB

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

• Patient must have previously been issued with an authority prescription for pazopanib, **AND**
• Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
• The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note** Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:  
Complete response (CR) is disappearance of all target lesions.  
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.  
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.  
Stable disease (SD) is small changes that do not meet above criteria.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

• Patient must have been receiving treatment with pazopanib prior to 1 October 2012, **AND**
• The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

### PONATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Prior Written Approval of Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

1. **Continuing treatment**  
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:  
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and  
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

2. **Authority approval requirements.**  
Response criteria to initial treatment with ponatinib:  
For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating...
the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib, nilotinib or ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

3. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib; **OR**
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib; **OR**
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; **OR**
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:  
1. Lack of response to dasatinib or nilotinib therapy, defined as either:  
   (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or  
   (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or  
   (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; **OR**
2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; **OR**
3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; **OR**
4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; **OR**
5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

**Accelerated phase** is defined by the presence of 1 or more of the following:  
1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  
3. Peripheral basophils greater than or equal to 20%; or  
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:  
1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  
2. Extramedullary involvement other than spleen and liver.

The authority application must be made in writing and must include:  
1. A completed authority prescription form;  
2. A completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form;  
3. A signed patient acknowledgement;  
4. A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report, which should be within the previous 6 months, needs to be provided); and  
5. where there has been a loss of response to dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Authority required**
Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must be expressing the T315I mutation, AND
- Patient must have failed an adequate trial of imatinib; OR
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have failed an adequate trial of nilotinib.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:
1. Lack of response to imatinib or dasatinib or nilotinib, defined as either:
   - (i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or
   - (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
   - (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

**Accelerated phase** is defined by the presence of 1 or more of the following:
1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

**Blast crisis** is defined as either:
1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and
3. a signed patient acknowledgement; and
4. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale and evidence of the T315I mutation. (The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided); and
5. where there has been a loss of response to imatinib or dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to ponatinib within 18 months of commencement and at no greater than 12 month intervals thereafter.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia Continuing PBS authority application Supporting information form; and
3. demonstration of continued response to treatment as evidenced by either:
   - (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
   - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

**note**: The relevant pathology report needs to be provided.
ponatinib 45 mg tablet, 30

ponatinib 15 mg tablet, 60

### PONATINIB

**Authority required**
Acute lymphoblastic leukaemia

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;
3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation. Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and
3. a signed patient acknowledgement; and
4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

Acute lymphoblastic leukaemia

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ponatinib 45 mg tablet, 30
RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required
High risk and intermediate-2 risk myelofibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Authority required
Intermediate-1 risk myelofibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Programs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required
High risk and intermediate-2 risk myelofibrosis
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

Note The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
(a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

Authority required
Intermediate-1 risk myelofibrosis
Treatment Phase: Initial treatment
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Clinical criteria:
- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

Note The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
c) A confirmation that the patient's disease-related symptoms are resistant, refractory or intolerant to available therapy.

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SORAFENIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, AND
- Patient must have a WHO performance status of 2 or less, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.
Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60
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SORAFENIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
• Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
• The treatment must be the sole PBS-subsidised therapy for this condition. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60

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**SORAFENIB**

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.
**Note** Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4230
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma
Treatment Phase: Initial
Clinical criteria:
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have a WHO performance status of 2 or less, AND
• Patient must have Child Pugh class A.

Authority required (STREAMLINED)

4234
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma
Treatment Phase: Continuing
Clinical criteria:
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have previously been treated with PBS-subsidised sorafenib, AND
• Patient must not have progressive disease.

sorafenib 200 mg tablet, 60

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**SUNITINIB**

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

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Initial treatment
Clinical criteria:
• Patient must be symptomatic (despite somatostatin analogues); OR
• Patient must have disease progression, AND
• The treatment must be as monotherapy.
Disease progression must be documented in the patient’s medical records.
Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.
Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

sunitinib 37.5 mg capsule, 28

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sunitinib 25 mg capsule, 28

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sunitinib 50 mg capsule, 28

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**SUNITINIB**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must not have disease progression, AND
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

sunitinib 37.5 mg capsule, 28
10473F

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10009T

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**SUNITINIB**

- **Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.
- **Note** Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.
- **Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
  - Complete response (CR) is disappearance of all target lesions.
  - Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
  - Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
  - Stable disease (SD) is small changes that do not meet above criteria.
- **Note** Special Pricing Arrangements apply.

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for sunitinib, AND
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

sunitinib 37.5 mg capsule, 28
10459L

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sunitinib 50 mg capsule, 28
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### SUNITINIB

**Note** Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

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

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

**Note** Special Pricing Arrangements apply.

<table>
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<td>Treatment Phase: Initial treatment</td>
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<td>Clinical criteria:</td>
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<td>• Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, <strong>AND</strong></td>
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<tr>
<td>• Patient must have a WHO performance status of 2 or less, <strong>AND</strong></td>
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<tr>
<td>• The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.</td>
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**Note** Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

**Note** Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

### METASTATIC OR UNRESECTABLE MALIGNANT GASTROINTESTINAL STROMAL TUMOUR

**Authority required**
- Metastatic or unresectable malignant gastrointestinal stromal tumour
- Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesylate.

Applications for authorisation must be in writing and must include:
1. A completed authority prescription form; and
2. A completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and
3. A signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

**Authority required**
- Metastatic or unresectable malignant gastrointestinal stromal tumour
- Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug, AND
- The treatment must be as monotherapy, AND
- Patient must have a WHO performance status of 2 or less, AND
- Patient must not have progressive disease.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

### sunitinib 37.5 mg capsule, 28

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### sunitinib 25 mg capsule, 28

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### sunitinib 50 mg capsule, 28

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### TRAMETINIB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 6778
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, AND
- Patient must not have had progressive disease when treated with a BRAF inhibitor.

### trametinib 500 microgram tablet, 30

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### TRAMETINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 6752
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, AND
- Patient must have stable or responding disease.

### trametinib 500 microgram tablet, 30

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</table>
### VEMURAFENIB

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Unresectable Stage III or Stage IV malignant melanoma</th>
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</thead>
<tbody>
<tr>
<td>Treatment Phase: Initial treatment</td>
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</tbody>
</table>

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; **OR**
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

### vemurafenib 240 mg tablet, 56

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

<table>
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<tr>
<td>Treatment Phase: Continuing treatment</td>
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</table>

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

### VEMURAFENIB

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

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<th>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</th>
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<tr>
<td>Treatment Phase: Initial treatment</td>
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**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
• Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), AND
• Patient must be inappropriate for chemo-immunotherapy.
A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:
1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x 10^9/L; or
2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x 10^9/L; or
3. Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).
Full blood count results must be no more than 1 month old at the time of application.
The authority application must be made in writing and must include:
a) A completed authority prescription form;
b) A completed CLL/SLL PBS Authority Application - Supporting information form; and
c) Pathology report indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:
   1) Recent severe neutropenia; or
   2) Recent severe thrombocytopenia; or
   3) Presence of 17p chromosomal deletion using fluorescence in situ hybridisation (FISH).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)
Treatment Phase: Continuing treatment
Clinical criteria:
• The treatment must be in combination with rituximab, AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

idelalisib 100 mg tablet, 60

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idelalisib 150 mg tablet, 60

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**IDELALISIB**

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Refractory follicular B-cell non-Hodgkin’s lymphoma
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must be refractory to a prior therapy with rituximab, AND
• The condition must be refractory to a prior therapy with an alkylating agent, AND
• The treatment must be the sole PBS-subsidised treatment for this condition.
The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.
The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.
The authority application must be made in writing and must include:
a) A completed authority prescription form; and
b) A completed Refractory follicular B-cell non-Hodgkin’s lymphoma PBS Authority Application - Supporting information form which must include date of completion of prior therapies with rituximab and an alkylating agent.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Authority required
Refractory follicular B-cell non-Hodgkin's lymphoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised treatment for this condition, AND
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Note: Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

idelalisib 100 mg tablet, 60

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- OLAPARIB

Note: Special Pricing Arrangements apply.

Authority required
High grade serous ovarian cancer
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be platinum sensitive, AND
- Patient must have received at least two previous platinum-containing regimens, AND
- Patient must have relapsed following a previous platinum-containing regimen, AND
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must be maintenance therapy, AND
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:
- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

Authority required
High grade serous fallopian tube cancer
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be platinum sensitive, AND
- Patient must have received at least two previous platinum-containing regimens, AND
- Patient must have relapsed following a previous platinum-containing regimen, AND
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must be maintenance therapy, AND
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:
- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

Authority required
High grade serous primary peritoneal cancer
Treatment Phase: Initial treatment
Clinical criteria:
- The condition must be platinum sensitive, AND
- Patient must have received at least two previous platinum-containing regimens, AND
- Patient must have relapsed following a previous platinum-containing regimen, AND
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must be maintenance therapy, AND
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:
- Patient must have evidence of a germline class 4 or 5 BRCA1 or BRCA2 gene mutation.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.
A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.
Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

olaparib 50 mg capsule, 4 x 112

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**OLAPARIB**

**Note** Special Pricing Arrangements apply.

**Authority required [STREAMLINED]**

6715
High grade serous ovarian cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must be maintenance therapy, AND
- Patient must not have progressive disease.

**Authority required [STREAMLINED]**

6705
High grade serous fallopian tube cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must be maintenance therapy, AND
- Patient must not have progressive disease.

**Authority required [STREAMLINED]**

6716
High grade serous primary peritoneal cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must be maintenance therapy, AND
- Patient must not have progressive disease.

olaparib 50 mg capsule, 4 x 112

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**VISMODEGIB**

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 9 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

**Authority required**
Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Initial treatment

Clinical criteria:
General

- The condition must be inappropriate for surgery, AND
- The condition must be inappropriate for curative radiotherapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and
b) a completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
f) A signed patient acknowledgement.

The assessment of the patient’s response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required
Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received an authority prescription for this condition with this drug, AND
- The condition must not have progressed, AND
- The condition must remain inappropriate for surgery, AND
- The condition must remain inappropriate for curative radiotherapy, AND
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and
b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and
c) A confirmation statement from the treating doctor that the disease has not progressed; and
d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient’s response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or
iii/ Limitations due to cumulative prior radiotherapy dose; or
iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required
Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Initial treatment or Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

VORINOSTAT
Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Authority required
Cutaneous T-cell lymphoma
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have received systemic treatment with chemotherapy, AND
- Patient must demonstrate relapsed or chemotherapy-refractory disease, AND
- Patient must be ineligible for stem cell transplant, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed cutaneous T-cell lymphoma (CTCL) initial PBS Authority Application - Supporting Information Form.

VORINOSTAT
Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Authority required
Cutaneous T-cell lymphoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

General Pharmaceutical Benefits 295
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

• Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

vorinostat 100 mg capsule, 120

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ENDOCRINE THERAPY

HORMONES AND RELATED AGENTS

Progestogens

MEDROXYPROGESTERONE

Restricted benefit

Advanced breast cancer
Clinical criteria:
• The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

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MEDROXYPROGESTERONE

Restricted benefit

Breast cancer
Clinical criteria:
• The condition must be hormone receptor positive.

Restricted benefit

Endometrial cancer

medroxyprogesterone acetate 200 mg tablet, 60

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medroxyprogesterone acetate 100 mg tablet, 100

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<thead>
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<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2725K</td>
<td>2</td>
<td>..</td>
<td>98.72</td>
<td>38.80</td>
<td>Provera [PF]</td>
</tr>
</tbody>
</table>

Gonadotropin releasing hormone analogues

GOSERELIN

Restricted benefit

Carcinoma of the prostate
Clinical criteria:
• The condition must be locally advanced (stage C); OR
• The condition must be metastatic (stage D).

goserelin 10.8 mg implant, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8093Y</td>
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<td>..</td>
<td>1050.60</td>
<td>38.80</td>
<td>Zoladex 10.8 Implant [AP]</td>
</tr>
</tbody>
</table>

GOSERELIN

Restricted benefit

Carcinoma of the prostate
Clinical criteria:
• The condition must be locally advanced (stage C); OR
• The condition must be metastatic (stage D).

Restricted benefit

Endometriosis
Clinical criteria:
• The condition must be visually proven, AND
• The condition must be for the short-term (up to 6 months).

Note Only 1 course of not more than 6 months’ therapy will be authorised.
### General Pharmaceutical Benefits

#### Restricted benefit

**Breast cancer**

**Clinical criteria:**
- The condition must be hormone receptor positive.

<table>
<thead>
<tr>
<th>goserelin 3.6 mg implant, 1</th>
<th>1454M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

**GOSERELIN (&) BICALUTAMIDE**

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

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

**Restricted benefit**

**Carcinoma of the prostate**

**Clinical criteria:**
- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

<table>
<thead>
<tr>
<th>goserelin 3.6 mg implant [1 implant] (&amp;) bicalutamide 50 mg tablet [28 tablets], 1 pack</th>
<th>9064C</th>
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<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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</tbody>
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<table>
<thead>
<tr>
<th>goserelin 10.8 mg implant [1 implant] (&amp;) bicalutamide 50 mg tablet [28 tablets], 1 pack</th>
<th>9065D</th>
</tr>
</thead>
<tbody>
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<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>goserelin 10.8 mg implant [1 implant] (&amp;) bicalutamide 50 mg tablet [84 tablets], 1 pack</th>
<th>9066E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

#### LEUPRORELIN

**Restricted benefit**

**Central precocious puberty**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; **OR**
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

<table>
<thead>
<tr>
<th>leuprorelin acetate 30 mg modified release injection [1 syringe] (&amp;) inert substance diluent [1 syringe], 1 pack</th>
<th>10255R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
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</tbody>
</table>

#### LEUPRORELIN

**Restricted benefit**

**Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate**

<table>
<thead>
<tr>
<th>leuprorelin acetate 30 mg injection: modified release [1] (&amp;) inert substance diluent [2 mL syringe], 1 pack</th>
<th>8877F</th>
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</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&amp;) inert substance diluent [1 syringe], 1 pack</th>
<th>8708H</th>
</tr>
</thead>
<tbody>
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<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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<tr>
<td>1</td>
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<table>
<thead>
<tr>
<th>leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&amp;) inert substance diluent [1 syringe], 1 pack</th>
<th>8707G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
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<td>1</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>leuprorelin acetate 22.5 mg injection: modified release [1] (&amp;) inert substance diluent [2 mL syringe], 1 pack</th>
<th>8876E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
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</tr>
</tbody>
</table>
leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

10656W

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>2021.67</td>
<td>38.80</td>
<td>Lucrin Depot 6-Month [VE]</td>
<td></td>
</tr>
</tbody>
</table>

leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

8859G

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>2021.67</td>
<td>38.80</td>
<td>Eligard 6 month [TL]</td>
<td></td>
</tr>
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</table>

leuprorelin acetate 7.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8875D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>393.95</td>
<td>38.80</td>
<td>Lucrin Depot 7.5mg PDS [VE]</td>
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leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8709J

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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1374.48</td>
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<td>Eligard 4 month [TL]</td>
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</table>

### LEUPRORELIN

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**
- Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), AND
- Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

**Restricted benefit**

Central precocious puberty

Treatment Phase: Initial - grandfather

**Clinical criteria:**
- Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

**Treatment criteria:**
- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

10256T

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1374.48</td>
<td>38.80</td>
<td>Lucrin Depot Paediatric 30 mg PDS [VE]</td>
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### LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE

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

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

**Restricted benefit**

Carcinoma of the prostate

**Clinical criteria:**
- The condition must be metastatic (stage D), AND
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

10962Y

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>472.21</td>
<td>38.80</td>
<td>Bi ELIGARD CP [TL]</td>
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leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

10963B

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<td>1123.38</td>
<td>38.80</td>
<td>Bi ELIGARD CP [TL]</td>
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leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack

10969H

<table>
<thead>
<tr>
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<tr>
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<td>1268.94</td>
<td>38.80</td>
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</table>
**TRIPTORELIN**

**Restricted benefit**
Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
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<td>38.80</td>
<td>Diphereline [IS]</td>
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</table>

**triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

<table>
<thead>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9379P</td>
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<td>1050.60</td>
<td>38.80</td>
<td></td>
<td>Diphereline [IS]</td>
</tr>
</tbody>
</table>

**triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9378N</td>
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<td>393.95</td>
<td>38.80</td>
<td></td>
<td>Diphereline [IS]</td>
</tr>
</tbody>
</table>

**HORMONE ANTAGONISTS AND RELATED AGENTS**

**Anti-estrogens**

**TAMOXIFEN**

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

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

**Restricted benefit**
Breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive.

**tamoxifen 10 mg tablet, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>21.26</td>
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<td>Genox 10 [AF]</td>
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</table>

**TAMOXIFEN**

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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

**Restricted benefit**
Breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>2</td>
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<td>27.82</td>
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<td>Nolvadex-D [AP]</td>
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</table>

**TAMOXIFEN**

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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

**Restricted benefit**
Breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive.

**tamoxifen 20 mg tablet, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>26.62</td>
<td>27.83</td>
<td></td>
<td>Genox 20 [AF]</td>
</tr>
</tbody>
</table>

\* GenRx Tamoxifen [GX]
\* Tamoxifen Sandoz [SZ]
## ANTI NEOPLASTIC AND IMMUNOMODULATING AGENTS

### TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

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

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

**Restricted benefit**

Reduction of breast cancer risk

**Clinical criteria:**
- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

<table>
<thead>
<tr>
<th>tamoxifen 20 mg tablet, 30</th>
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</thead>
<tbody>
<tr>
<td><strong>10911G</strong></td>
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<tr>
<td>Max Qty Packs</td>
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### TOREMIFENE

toremifene 60 mg tablet, 30

**8216K**

<table>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>69.23</td>
<td>38.80</td>
<td>Fareston [AS]</td>
</tr>
</tbody>
</table>

### BICALUTAMIDE

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

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

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

**Authority required (STREAMLINED)**

5729

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**
- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

<table>
<thead>
<tr>
<th>bicalutamide 50 mg tablet, 28</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8094B</strong></td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<td>---</td>
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<tr>
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### CYPROTERONE

cyproterone acetate 50 mg tablet, 50

**1270W**

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*82.69</td>
<td>38.80</td>
<td>* ANTERONE 50 [RW]</td>
<td>* Cyproc 50 [QA]</td>
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<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*84.97</td>
<td>38.80</td>
<td>* Cyproterone Acetate [GX]</td>
<td>* Cyprostat-100 [SY]</td>
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<table>
<thead>
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<tbody>
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<td>Max Qty Packs</td>
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<td>---</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
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</tbody>
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**Notes:**
- **NP** indicates non-prescription.
- **RP** indicates restricted prescription.
- **P** indicates prescription.
- **D** indicates dispensing.
- **M** indicates management.
- **S** indicates substitution.
- **V** indicates visit.
- **N** indicates notification.
- **G** indicates general.
- **R** indicates restricted.
- **A** indicates arm.
- **P** indicates prescription.
- **D** indicates dispensing.
- **M** indicates management.
- **S** indicates substitution.
- **V** indicates visit.
- **N** indicates notification.
- **G** indicates general.
- **R** indicates restricted.
- **A** indicates arm.

**Clinical criteria:**
- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.
ENZALUTAMIDE

- **Note** Special Pricing Arrangements apply.
- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; **OR**
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must not have received prior treatment with abiraterone; **OR**
- Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

**enzalutamide 40 mg capsule, 112**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tr>
<td>1</td>
<td>2</td>
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<td>3720.82</td>
<td>38.80</td>
<td>Xtandi [LL]</td>
</tr>
</tbody>
</table>

FLUTAMIDE

- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Shared Care Model:
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Clinical criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The treatment must be in combination with GnRH (LH-RH) analogue therapy.</td>
</tr>
</tbody>
</table>

**flutamide 250 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*154.30</td>
<td>38.80</td>
<td>Flutamide MYLAN [AF]</td>
</tr>
</tbody>
</table>

FLUTAMIDE

- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Shared Care Model:
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Clinical criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The treatment must be in combination with GnRH (LH-RH) analogue therapy.</td>
</tr>
</tbody>
</table>

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1†</td>
<td>5</td>
<td>..</td>
<td>472.21</td>
<td>38.80</td>
<td>Bi ELIGARD CP [TL]</td>
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</table>
### Leuprorelin Acetate 22.5 mg Modified Release Injection [1 Syringe] (&) Inert Substance Diluent [1 Syringe] (&) Bicalutamide 50 mg Tablet [28], 1 Pack

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10963B</td>
<td></td>
<td></td>
<td></td>
<td>1123.38</td>
<td>38.80</td>
<td>Bi ELIGARD CP [TL]</td>
</tr>
</tbody>
</table>

### Leuprorelin Acetate 22.5 mg Modified Release Injection [1 Syringe] (&) Inert Substance Diluent [1 Syringe] (&) Bicalutamide 50 mg Tablet [84], 1 Pack

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>10969H</td>
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<td></td>
<td>1268.94</td>
<td>38.80</td>
<td>Bi ELIGARD CP [TL]</td>
</tr>
</tbody>
</table>

### Nilutamide

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

### Anastrozole

**Note**
This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note**
This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

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

### Exemestane

**Restricted benefit**
Metastatic (Stage IV) breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive, AND
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**
- Patient must not be pre-menopausal.
**EXEMESTANE**

*Note* This drug is not PBS-subsidised for primary prevention of breast cancer.

*Note* This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

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

**Restricted benefit**

**Breast cancer**

**Clinical criteria:**
- The condition must be hormone receptor positive.

### exemestane 25 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Exemestane [TX]</td>
<td>66.59</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>Examane [JU]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exaccord [RA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exemestane GH [GQ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exemestane Sandoz [SZ]</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**LETROZOLE**

*Note* This drug is not PBS-subsidised for primary prevention of breast cancer.

*Note* This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

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

**Restricted benefit**

**Breast cancer**

**Clinical criteria:**
- The condition must be hormone receptor positive.

### letrozole 2.5 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Letrozole [TX]</td>
<td>30.88</td>
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</tr>
<tr>
<td>Femara 2.5 mg [NV]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fera [QA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letroz [JU]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letrozole FBM [FO]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Letrozole RBX [RA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacor Letrozole 2.5 [CR]</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Chem mart Letrozole [CH]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Femolet [AF]</td>
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<td></td>
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</tr>
<tr>
<td>Gynotril [ER]</td>
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<td></td>
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<tr>
<td>Letrozole AN [EA]</td>
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<tr>
<td>Letrozole generichealth [GQ]</td>
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<tr>
<td>Letrozole Sandoz [SZ]</td>
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<tr>
<td>Terry White Chemists Letrozole [TW]</td>
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</tbody>
</table>

**Other hormone antagonists and related agents**

**ABIRATERONE**

*Note* Special Pricing Arrangements apply.

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**
- The treatment must be used in combination with a corticosteroid, AND
- The treatment must not be used in combination with chemotherapy, AND
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND
- Patient must have a WHO performance status of 2 or less, AND
- Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, AND
- Patient must not have received prior treatment with enzalutamide; OR
- Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

### abiraterone acetate 250 mg tablet, 120

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Abibaterone [TX]</td>
<td>3603.06</td>
<td>38.80</td>
</tr>
</tbody>
</table>

**DEGARELIX**

**Restricted benefit**
**DEGARELIX**

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2784M</td>
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<td>5</td>
<td>393.95</td>
<td>38.80</td>
<td>Firmagon 80mg [FP]</td>
</tr>
</tbody>
</table>

**degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2785N</td>
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<td>..</td>
<td>412.15</td>
<td>38.80</td>
<td>Firmagon 120mg [FP]</td>
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</tbody>
</table>

**IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

**INTERFERON ALFA-2A**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Myeloproliferative disease

**Clinical criteria:**
- Patient must have excessive thrombocytosis.

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8553E</td>
<td>5</td>
<td>4</td>
<td>*477.25</td>
<td>38.80</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8181N</td>
<td>15</td>
<td>5</td>
<td>*477.40</td>
<td>38.80</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8184R</td>
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<td>5</td>
<td>*477.25</td>
<td>38.80</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**INTERFERON ALFA-2B**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**
Hairy cell leukaemia

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

8572E

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>4</td>
<td>..</td>
<td>*571.66</td>
<td>38.80</td>
<td>Intron A Redipen [MK]</td>
</tr>
</tbody>
</table>

### INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Multiple myeloma

**Treatment Phase:** Maintenance treatment

**Clinical criteria:**
- The condition must be in remission following chemotherapy.

**Authority required**

Low grade non-Hodgkin’s lymphoma

**Clinical criteria:**
- The condition must have clinical features suggestive of a poor prognosis, AND
- The treatment must be in combination with anthracycline-based chemotherapy.

**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

8476D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
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<td>..</td>
<td>*949.60</td>
<td>38.80</td>
<td>Intron A Redipen [MK]</td>
</tr>
</tbody>
</table>

**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

8348J

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*571.66</td>
<td>38.80</td>
<td>Intron A Redipen [MK]</td>
</tr>
</tbody>
</table>

### INTERFERON BETA-1A

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

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

**Authority required (STREAMLINED)**

4881

Multiple sclerosis

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

6860

Multiple sclerosis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not show continuing progression of disability while on treatment with this drug, AND
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges**

9332E

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>998.56</td>
<td>38.80</td>
<td>Rebif 44 [SG]</td>
</tr>
</tbody>
</table>

**interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes**

8403G

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>998.56</td>
<td>38.80</td>
<td>Rebif 44 [SG]</td>
</tr>
</tbody>
</table>

**INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12**

8968B

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>998.56</td>
<td>38.80</td>
<td>Rebif 44 [SG]</td>
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</tbody>
</table>
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

### INTERFERON BETA-1B

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

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

**Authority required (STREAMLINED)**

**4881**

Multiple sclerosis

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

**Authority required (STREAMLINED)**

**6860**

Multiple sclerosis

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not show continuing progression of disability while on treatment with this drug, AND
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

### PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

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

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

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 12 weeks.

### PEGINTERFERON BETA-1A

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

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

**Authority required (STREAMLINED)**

**4881**

Multiple sclerosis

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Antineoplastic and Immunomodulating Agents**

**Peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>..</td>
<td>1050.09</td>
<td>38.80</td>
<td>Plegridy [BD]</td>
</tr>
</tbody>
</table>

**Peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) Peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>1050.09</td>
<td>38.80</td>
<td>Plegridy [BD]</td>
</tr>
</tbody>
</table>

**Peginterferon Beta-1A**

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

**Authorised (STREAMLINED)**

**6860**  
Multiple sclerosis  
Treatment Phase: Continuing treatment  
**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Bacillus Calmette and Guerin-Tice strain**

**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

**Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 vials**

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**Glatiramer Acetate**

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

**Authority required (STREAMLINED)**

**4881**  
Multiple sclerosis  
Treatment Phase: Initial treatment  
**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**6860**  
Multiple sclerosis  
Treatment Phase: Continuing treatment  
**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must not show continuing progression of disability while on treatment with this drug, **AND**
• Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes

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glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes

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**IMMUNOSUPPRESSANTS**

**Selective immunosuppressants**

**ABATACEPT**

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
• Patient must have a documented history of severe active rheumatoid arthritis, **AND**
• Patient must have demonstrated an adequate response to treatment with this drug, **AND**
• Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Switching therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Abatacept patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most
recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Where applications are submitted and the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, the 6 to 12 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
abatacept 125 mg/mL injection, 4 x 1 mL syringes

11068M

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abatacept 125 mg/mL injection, 4 x 1 mL syringes

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**ABATECEPT**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) lefunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) lefunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, lefunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tolizumab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. completed authority prescription forms; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

**Initial treatment with an I.V. loading dose:** Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

**Initial treatment with no loading dose:** One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

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

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
Further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints, response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

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

**Note**

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

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription forms; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

**Initial treatment with an I.V. loading dose:** Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

**Initial treatment with no loading dose:** One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- An ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient who has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose
based on the patient’s weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Authority required**
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

abatacept 125 mg/mL injection, 4 x 1 mL syringes

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EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

everolimus 750 microgram tablet, 60

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FINGOLIMOD

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Multiple sclerosis
Treatment Phase: Initial treatment
Clinical criteria:
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
- Patient must be ambulatory (without assistance or support).
Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required
Multiple sclerosis
Treatment Phase: Continuing treatment
Clinical criteria:
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not show continuing progression of disability while on treatment with this drug, AND
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**fingolimod 500 microgram capsule, 28**

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**LEFLUNOMIDE**

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5766
Severe active psoriatic arthritis

Clinical criteria:
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, AND
- The treatment must be initiated by a physician.

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**LEFLUNOMIDE**

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5681
Severe active rheumatoid arthritis

Clinical criteria:
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, AND
- The treatment must be initiated by a physician.

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**MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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### MYCOPHENOLATE

**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

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### SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

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### TERIFLUNOMIDE

**Caution** Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple sclerosis  
Treatment Phase: Initial treatment  

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient. **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition. **AND**
• Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
• Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

**Authority required**

Multiple sclerosis
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

teriflunomide 14 mg tablet, 28

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**TOFACITINIB**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent course of PBS-subsidised bDMARD treatment was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding
rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course treatment. Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to re qualify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

General Pharmaceutical Benefits

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Special Pricing Arrangements apply.

### Authority required
Severe active rheumatoid arthritis

### Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tofacitinib 5 mg tablet, 56

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**TOFACITINIB**

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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Patients are eligible for PBS-subsidised bDMARD treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
   (a) Initial treatment.
   Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
   (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
   (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

   Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

   Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

   A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

   Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

   For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   Abatacept patients:
   Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

   Rituximab patients:
   A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

   (b) Continuing treatment.

   Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure...
uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**

**Note:** If you are a doctor, pharmacist, or丝路 policy maker, please make sure you understand the implications of these restrictions before implementing them.
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

• Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

• an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.
Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
• Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.
The authority application must be made in writing and must include:
(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.
An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 3 (Grandfather patients)

Clinical criteria:
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2015, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(c) a signed patient acknowledgement.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Tumor necrosis factor alpha (TNF-) inhibitors

#### ADALIMUMAB

Note Special Pricing Arrangements apply.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to: Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab. From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment to ensure adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the terms of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg per 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**
Severe Crohn disease
Treatment Phase: Balance of supply for paediatric patient

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Initial 3 (grandfathered patients) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 16 weeks of therapy (new patients or change/recommencement patients; Initial 1 or Initial 2) or 24 weeks of therapy (Continuing patients or Grandfathered patients).

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

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

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**ADALIMUMAB**

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Note Special Pricing Arrangements apply.

**Authority required**
Moderate to severe hidradenitis suppurativa
Treatment Phase: Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment – balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment.

**Treatment criteria:**
- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges**

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<th>No. of Rpts</th>
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**ADALIMUMAB**

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
• Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is determined according to the reduction in the total number of active joints, the response will be determined by the reduction in the total number of active joints.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

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

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

---

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
ADALIMUMAB

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 April 2011 is considered to be in their first treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

These interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 April 2011 is considered to be in their first treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alpha antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alpha antagonist.

For second and subsequent courses of PBS-subsidised TNF-alpha antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alpha antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alpha antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alpha antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab or infliximab prior to 1 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

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

Authority required

Initial 1

Initial treatment of complex refractory Fistulising Crohn Disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.
It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270


Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

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### ADALIMUBAB

**Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:
TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have responded to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.
Antineoplastic and immunomodulating agents

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) is receiving treatment with adalimumab at the time of application; and
(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of complex refractory fistulising Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### ADALIMUMAB

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Moderate to severe hidradenitis suppurativa

**Clinical criteria:**
- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; **OR**
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**
- Must be treated by a dermatologist.
- Assessment of disease severity must be no more than 1 month old at the time of application.

An assessment of the patient’s response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:

(i) the Hurley stage grading; and
(ii) the AN count; and
(iii) the name of the antibiotic/s received for two separate courses each of three months; or
(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
(v) a signed patient acknowledgement.

**Authority required**

**Moderate to severe hidradenitis suppurativa**

**Treatment Phase: Initial treatment 2 - Recommencement of treatment**

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

 Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An assessment of the patient’s response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:

(i) the Hurley stage grading; and
(ii) the AN count.

**adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

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**ADALIMUMAB**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note**  Special Pricing Arrangements apply.

**Authority required**

**Moderate to severe hidradenitis suppurativa**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

 Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.
The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed hidradenitis suppurativa PBS authority application supporting information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**Authority required**

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 3 - Grandfathered patient

**Clinical criteria:**

- Patient must have been receiving treatment with this drug for this condition prior to 1 July 2017, AND
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug, AND
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, AND
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have contraindication to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.
- A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.
- For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.
- The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Assessment of disease severity must be no more than 1 month old at the time treatment with this drug was initiated.
- A maximum of 24 weeks treatment will be authorised under this restriction.
- A patient may qualify for PBS-subsidised treatment under this restriction once only.
- For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or recommencement of treatment criteria where there is a break in treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) completed hidradenitis suppurativa PBS authority application supporting information form which must include:

(i) the Hurley stage grading; and
(ii) the AN count; and
(iii) the name of the antibiotic/s received for two separate courses each of three months; or
(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
(v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment
(vi) a signed patient acknowledgement.

**adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges**

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**ADALIMUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:
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Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ’Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

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

From 1 September 2017, a patient must be assessed for response to any course of PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

(6) Patients ‘grandfathered’ onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

**Authority required**

**Severe Crohn disease**

Treatment Phase: Continuing treatment

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no
Antineoplastic and immunomodulating agents

Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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Adalimumab

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will be authorised.

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Treatment of Paediatric Patients with Refractory Crohn Disease

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

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

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Note Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces:
normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will be authorised.

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Treatment of Paediatric Patients with Refractory Crohn Disease

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

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

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved outlined in the restriction for continuing treatment.

Treatment criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND

- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI

(Initial 1)

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND

- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND

- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

- Must be treated by a paediatrician; OR

- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

- (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient’s condition; and

- (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

- (iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under
10389T
adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

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no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI

(Initial 2)

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Population criteria:**
- Patient must be aged 6 to 17 years inclusive.

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

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription form; and
(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges
10397F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 3989.10 38.80 Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
10419J
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 1401.83 38.80 Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes
10404N
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 6 3989.10 38.80 Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges
10413C
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 1401.83 38.80 Humira [VE]

**ADALIMUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "tumour necrosis factor (TNF) alfa antagonist" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

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

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

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

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose).
for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (e.g. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with this drug (Initial 3 - Grandfather)

**Treatment criteria:**

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

Clinical criteria:
- Patient must have been receiving treatment with this drug prior to 1 August 2015, **AND**
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have had disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on prior conventional treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:
- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed paediatric Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet;
(ii) the date of commencement of this drug; and
(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The patient's current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with this drug.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

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

Authority required
Severe Crohn disease
Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:
- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:
- Patient must be aged 6 to 17 years inclusive.

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

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.
If the application is the first application for continuing treatment with adalimumab, a PCDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

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

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

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### ADALIMUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; **OR**
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.
- For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

- The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
  - (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
  - (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
  - (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time. From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only. Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy.

The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy to the date of the first application for initial treatment. A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment.

There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  - (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  - (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**ADALIMUMAB**

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

**Authority required**  
Ankylosing spondylitis  
Treatment Phase: Continuing treatment

**Clinical criteria:**  
- Patient must have a documented history of active ankylosing spondylitis, AND  
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND  
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**  
- Patient must be an adult.

**Treatment criteria:**  
- Must be treated by a rheumatologist.  
An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:  
(a) an ESR measurement no greater than 25 mm per hour; or  
(b) a CRP measurement no greater than 10 mg per L; or  
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.  
The authority application must be made in writing and must include:  
(a) a completed authority prescription form; and  
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.  
All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.  
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**  
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS  
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.  
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.  
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy  
(a) Initial treatment.  
Applications for initial treatment should be made where:  
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or  
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or  
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).  
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.  
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

Following the completion of an initial treatment course with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

**Treatment Phase: Continuing treatment – balance of supply**

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be
ADALIMUMAB

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term...
bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
   (a) Initial treatment.
   Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
   (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
   (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

   Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

   Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

   A patient must be assessed for response to therapy, following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

   Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

   For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   Abatacept patients:

   Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

   Rituximab patients:

   A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

   (b) Continuing treatment.

   Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

   Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients:

   A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

   Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient
will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 8741C**

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ADALIMUMAB

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

Note: No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note: Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below).

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Note: Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

1. Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.


Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

3. Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

4. Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

5. Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of
at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### Authority required

Severe psoriatic arthritis

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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### ADALIMUMAB

**Note** **TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and
Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a further course of treatment within the same treatment cycle.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a
new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.(a) Initial treatment.Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) (further details are under 'Swapping treatment' below); or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted, the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted treatment. Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior course of conventional therapies of anti-tumour necrosis factor-alfa antagonists. A patient may only swap to another TNF-alfa antagonist regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity established at baseline at the commencement of treatment with each treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase:** Initial treatment (new patient or Recom mencement of treatment after more than 5 years break in therapy - Initial 1)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**
Note
At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment for the initial 24 months of treatment of an appropriately dosed thiopurine agent, AND

- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, AND

- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:
- Patient must be 6 years of age or older.

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:(a) two completed authority prescription forms; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and(iii) the signed patient acknowledgement or guardian acknowledgement.

For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note
At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001
Must be treated by a gastroenterologist (code 87); OR
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician; OR
Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**
- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
- the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
- details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Note** At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

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**Adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges**

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**ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the latest approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

1. **How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016.**

   (a) **Initial treatment.** Applications for initial treatment should be made where:

   (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

   (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

   (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

   Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

   A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   (b) **Continuing treatment.**

   Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised treatment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

2. **Swapping therapy.**

   Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

3. **Baseline measurements to determine response.**

   The Department of Human Services will determine whether a response to treatment has been demonstrated based on the...
baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 6 consecutive months or oral steroids over a 6 week period preceding the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’ treatment restriction. A patient who only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either ceased or failed to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017. (a) Initial treatment. Applications for initial treatment should provide where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping treatment’ below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised treatment with that agent (Initial 2). Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. (2) Swapping treatment. Once
initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate agent at any time, regardless of whether treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured. (5) Patients ‘grandfather’ patients) who commenced treatment with infliximab or adalimumab at baseline prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, while receiving treatment with this drug. **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81); **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82); **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Written response assessment and must be submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services
Complex Drugs
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Initial 3 (Grandfathered patient)

Clinical criteria:
- Patient must have a documented history of moderate to severe ulcerative colitis, AND
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, AND
- Patient must be receiving treatment with this drug at the time of application, AND
- Patient must have a Mayo score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have a partial Mayo score is greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 6 prior to commencing treatment with this drug, if aged 6 to 17 years; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, if aged 6 to 17 years, AND
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:
- Patient must be 6 years of age or older.

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheets including the dates of assessment of the patient's condition; and (ii) the date of commencement of this drug; and (iii) the signed patient or guardian acknowledgement

The current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Balance of supply for Continuing treatment and Initial 3 (Grandfathered patients)

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial 3 (Grandfathered patients).

Population criteria:
- Patient must be 6 years of age or older.
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81); OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82); OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

11121H

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10960W

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

10961X

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**ADALIMUMAB**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**
- Patient must not have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/d; and/or (iii) sodium aurothiomalate at a dose of 50 mg daily, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270.

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- a patient from the requirement for a 6 month trial of intensive DMARD therapy.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

Note

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

Reports of any side effects of the drug, together with the toxicities and other relevant documentation (as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Applications for patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the application, the same marker will be used to determine response.

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who...
has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the...
required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note  No increase in the maximum quantity or number of units may be authorised.

Note  No increase in the maximum number of repeats may be authorised.

Note  Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**
- Patient must be aged 18 years or older.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- a patient who has either failed to respond to treatment 5 times, or who has had a break in therapy of less than 24 months, will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction.
A patient who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to...
treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment. **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.
Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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ADALIMUMAB

Note No increase in the maximum number of repeats may be authorised.

Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)
Clinical criteria:
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; **AND**
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.
The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.
Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.
The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note: Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au.

Note: For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au.

**Authority required**

**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis. **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle. **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle. **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
- Department of Human Services Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARD at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients – secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:
• Patient must have active, or a documented history of active, ankylosing spondylitis, AND
• Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:
• Patient must be an adult.
Treatment criteria:
- Must be treated by a rheumatologist.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ADALIMUMAB**

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 16 weeks for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

On commencement of treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment under the prescribed condition, may be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Note No applications for increased maximum quantities will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

**Authority required**

Severe Crohn disease
Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician (general medicine specialising in gastroenterology (code 82)); OR
- Must be treated by a consultant physician (internal medicine specialising in gastroenterology (code 81)); OR

**Clinical criteria:**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**
- Patient must be aged 18 years or older.

**Clinical criteria:**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
- (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
- (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
- (iv) the date of the most recent clinical assessment; and
- (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.
Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note: No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe Crohn disease

**Treatment Phase: Change or Re-commencement of treatment (initial 2)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, AND
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment; and
(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note: No increase in the maximum number of repeats may be authorised.
**Authority required**
Severe Crohn disease
Treatment Phase: Balance of supply

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the initial dose (i.e. the initial infusion regimen at weeks 0 and 2); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 2 doses (new patients) or 5 repeats (Continuing treatment).

**Population criteria:**
- Patient must be aged 18 years or older.
Authority approval for sufficient therapy to complete a maximum of 2 initial doses or 5 repeats may be requested by telephone by contacting the Department of Human Services.

**Note**
No increase in the maximum quantity or number of units may be authorised.

### ADALIMUMAB

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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### ADALIMUMAB 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

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General

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Note

- Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

- The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

- Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

- Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.
An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who have failed treatment fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological treatment and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, and 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who have failed treatment fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, and 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment must be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of...
Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone. Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment. AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Note: TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. (3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(7) Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes
the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the
patient's condition.
The most recent PASI assessment must be no more than 1 month old at the time of application.
Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of
treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to
the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a
response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the
patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the
Department of Human Services on 1800 700 270 to discuss.
Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the
patient completing their current treatment course to ensure continuity of treatment for those patients who meet the
continuation criterion for PBS-subsidised treatment with this drug.
Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this
Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment
Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent
was approved in this Cycle and the date of the first application under the new Cycle.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Face, hand, foot
Clinical criteria:
• Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a
foot, AND
• Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for
this condition in the current Treatment Cycle, AND
• Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this
restriction.
Population criteria:
• Patient must be aged 18 years or older.
Treatment criteria:
• Must be treated by a dermatologist.
For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or
ustekinumab.
An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and
scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological
treatment baseline value.
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of
PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment
course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an
assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.
Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to
respond to treatment with this drug.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes
the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including
the date of the assessment of the patient's condition.
The most recent PASI assessment must be no more than 1 month old at the time of application.
Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.
The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.
Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of
treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to
the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note**

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

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**ADALIMUMAB**

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required**
Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
For the purposes of this restriction ‘biological agent’ means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction ‘biological agent’ means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:
- A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Antineoplastic and Immunomodulating Agents

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where:
  - (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
  - (i) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
  - (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
  - (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
- (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
  - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
  - (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
  - (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  - (iii) the signed patient and prescriber acknowledgements.

Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note
A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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CERTOLIZUMAB PEGOL

Note Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, AND
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.
### CERTOLIZUMAB PEGOL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

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### CERTOLIZUMAB PEGOL

**Note** Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Special Pricing Arrangements apply.**

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
cetolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

**CERTOLIZUMAB PEGOL**

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, cetolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note:**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A
General Pharmaceutical Benefits

patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may try an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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**CERTOLIZUMAB PEGOL**

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a
disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

The PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Exception as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have severe active rheumatoid arthritis, AND
• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
• Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times., AND
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment...
with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**

- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence treatment with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Clinical criteria:
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
  For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
  AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**CERTOLIZUMAB PEGOL**

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

**Authority required**
Ankylosing spondylitis
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
  (a) an ESR measurement no greater than 25 mm per hour; or
  (b) a CRP measurement no greater than 10 mg per L; or
  (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note: TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

**Initial treatment.**

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) **Grandfather patients - secukinumab only.**

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(c) **Continuing treatment.**

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. (2) **Swapping therapy.**

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is
important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis
Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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CERTOLIZUMAB PEGOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, AND
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing
Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender.

**Population criteria:**
- Patient must be an adult.
- **Treatment criteria:**
  - Must be treated by a rheumatologist.
  
  The application must include details of the NSAIDs trialled, their doses and duration of treatment.

  If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

  If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

  If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

  The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

  (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
  (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

  The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

  Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

  The authority application must be made in writing and must include:
  (a) a completed authority prescription form; and
  (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
    (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
    (ii) a completed BASDAI Assessment Form; and
    (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
    (iv) a signed patient acknowledgment.

  The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

  A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

  Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e., for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note: TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient may continue to receive long-term treatment with only 1 of the 6 bDMARDs at any 1 time.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment. Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
   (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
   (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may try an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Certolizumab Pegol**

**Note**

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy. Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular Treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy.
requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment - balance of supply
Clinical criteria:
• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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CERTOLIZUMAB PEGOL

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

The purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note:**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under "(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis:

1. Initial treatment.
   - Applications for initial treatment should be made where:
     - (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
     - (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy below]; and
     - (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with...
that specific agent (Initial 1 or Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Certolizumab Pegol 200 mg/mL Injection, 2 x 1 mL syringes**

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**ETANERCEPT**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have demonstrated an adequate response to treatment with etanercept, AND
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
  - (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  - (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  - (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time. From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of...
the first application for initial treatment with a bDMARD under the new treatment cycle. A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to completing their current course treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Treatment criteria:

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

• Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.
ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

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**ETANERCEPT**

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- either of the following:
  - a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with a PBS-subsidised bDMARD was provided to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to recommence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that ceasing was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframe, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure
uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
ETANERCEPT

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly; OR
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
- If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
- The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.
- The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.
- If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.
- The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or...
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, ciclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient...
will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to re-qualify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

**Severe active juvenile idiopathic arthritis**

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

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### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

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### ETANERCEPT

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

...
• Patient must be aged 18 years or older.

Clinical criteria:

• Patient must have severe active rheumatoid arthritis, AND

• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

• Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met by using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The Joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised treatment was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may recommence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised treatment with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the initial application), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to...
the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)**

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
• Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a
Further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD therapy and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient is reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

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**ETANERCEPT**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

---

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note: TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any one time. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

1. How to prescribe PBS-subsidised bDMARD therapy
   (a) Initial treatment.

   Applications for initial treatment should be made where:

   (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
   (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
   (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

   A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

   For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   (b) Grandfather patients - secukinumab only.

   For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

   Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

   (c) Continuing treatment.

   Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24
weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

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etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

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### ETANERCEPT

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

- Severe psoriatic arthritis
- Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### Population criteria:

- Patient must be an adult.

#### Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible...
to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy ( Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be
provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

**Treatment Phase: Continuing treatment - balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

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**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**ETANERCEPT**

**Active ankylosing spondylitis**

**Treatment Phase: Initial 1 (new patients)**

**Clinical criteria:**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
- Patient must be an adult.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment criteria:

- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis. AND

- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle. AND

- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle. AND

- Patient must be eligible to receive further bDMARD therapy.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.
years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and
the date of the first application under a new cycle.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab,
certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept,
golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term
therapy with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD
more than once.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment
cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible
to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD
treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new
treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years
may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years
may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such
therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent
(Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with
that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5
years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks
of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the
date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient
will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in
the month prior to completing their current course of treatment and that an application is posted to the Department of Human
Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications
for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial
3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been
treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of
treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24
weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The
patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing
they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure
uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD
within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the
erthrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and
exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing)
with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to
respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is
important that they are assessed for response to every course of treatment approved, within the timeframes specified in the
relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

### Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:
- Patient must have active, or a documented history of active, ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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### ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

### Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
- Patient must have severe active psoriatic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
• Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
• Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
• Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be an adult.
**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The application authority must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

**How to prescribe biological agents for the treatment of severe active psoriatic arthritis.**

1. **Initial treatment.** Applications for initial treatment should be made where:
   - (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Severe psoriatic arthritis
   Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
   Department of Human Services
   Complex Drugs
   Reply Paid 9826
   HOBART TAS 7001

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

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etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

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ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1);
or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(5) Baseline measurements to determine response.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

When a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Authority required**

**Severe chronic plaque psoriasis**

**Treatment Phase: Continuing treatment, Whole body**

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
• Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **AND**
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
• Patient must be aged 18 years or older.

**Treatment criteria:**
• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Face, hand, foot

**Clinical criteria:**
• Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
• Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
• Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **AND**
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
• Patient must be aged 18 years or older.

**Treatment criteria:**
• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If this application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Note

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment.

Note

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:
- Must be treated by a dermatologist.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

etanercept 25 mg injection [4 vials] & inert substance diluent [4 x 1 mL syringes], 1 pack

**ETANERCEPT**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

**Severe chronic plaque psoriasis**

**TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

**Treatment criteria:**
- Must be treated by a dermatologist.

**Population criteria:**
- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Clinical criteria:**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, AND
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, AND
- Patient must not have achieved an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply**

**TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.
There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.
Applications for re-treatment with etanercept should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:
Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:
Patients are eligible for re-treatment due to disease flare if:
(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course
Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.
The PASI assessment must be conducted after at least 12 weeks of treatment.
This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.
The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:
- Must be treated by a dermatologist.
Clinical criteria:
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate. AND
- Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.
Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:
- Must be treated by a dermatologist.

Clinical criteria:
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, AND
- Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, AND
- Patient must have demonstrated an adequate response to treatment, AND
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre- etanercept treatment baseline value.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and...
(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient’s condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient’s response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note**
It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note**
In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au).

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Re-treatment (Whole body)

**TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy;

or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances
where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.
The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score. To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:
• Must be treated by a dermatologist.

Population criteria:
• Patient must be under 18 years of age.

Clinical criteria:
• The treatment must be as systemic monotherapy; OR
• The treatment must be in combination with methotrexate, AND
• Patient must have a documented history of severe chronic plaque psoriasis of the whole body, AND
• Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, AND
• Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
• Patient must not have failed more than once to achieve an adequate response with etanercept, AND
• Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patient’s PASI score or the assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for further treatment.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.
Applications for re-treatment with etanercept should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, AND
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criteria indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient’s condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances
where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

• Must be treated by a dermatologist.

Clinical criteria:

• The treatment must be as systemic monotherapy; OR
• The treatment must be in combination with methotrexate, AND
• Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment from the date the most recent treatment was stopped to the date of the first application for initial treatment.

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There are separate restrictions for treatment from the date the most recent treatment was stopped to the date of the first application for initial treatment.
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

• Must be treated by a dermatologist.

Clinical criteria:

• The treatment must be as systemic monotherapy; OR
• The treatment must be in combination with methotrexate, AND
• Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR
• Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, AND
• Patient must have demonstrated an adequate response to treatment, AND
• Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient’s condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient’s response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

**Note**

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note**

In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis
Treatment Phase: Re-treatment (Face, hand, foot)
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.
Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.
Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.
There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.
(2) Applications for approval for re-treatment.
Applications for re-treatment should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy;
or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.
For psoriasis affecting the whole body:
Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.
For psoriasis affecting the face, hand or foot:
Patients are eligible for re-treatment due to disease flare if:
(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.
(3) Applications for approval for completion of a course
Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.
The PASI assessment must be conducted after at least 12 weeks of treatment.
This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.
(4) Baseline measurements to determine response.
The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.
(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.
Treatment criteria:
- Must be treated by a dermatologist.
Population criteria:
- Patient must be under 18 years of age.
Clinical criteria:
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, AND
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, AND
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, AND
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.
A patient is eligible for re-treatment due to disease flare if:
(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition; and
(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

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### ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 1) [further details are under ‘(4) Swapping therapy’ below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

When a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recomencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
• Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
• Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**
• Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
• Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
• Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **AND**
• Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

• Patient must be aged 18 years or older.

**Treatment criteria:**

• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted as the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

*Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)*
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.
- For the purposes of this restriction ‘biological agent’ means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
- The authority application must be made in writing and must include:
  (a) a completed authority prescription form; and
  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
     (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition; and
     (ii) details of prior biological treatment, including dosage, date and duration of treatment.
- Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.
- An adequate response to treatment is defined as:
  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii)
cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

- The treatment must be as systemic monotherapy (other than methotrexate), AND

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
There is no natural text in the image provided.
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
• Must be treated by a dermatologist.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### ETANERCEPT

**Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

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### GOLIMUMAB

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
• Patient must have a documented history of severe active rheumatoid arthritis, **AND**
• Patient must have demonstrated an adequate response to treatment with this drug, **AND**
• Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
• Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD while they continue to show a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of more than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must re qualify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New...
General

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) or the relevant State Human Services agency.

General Pharmaceutical Benefits  465

Baseline measurements may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

Treatment criteria:

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have severe active rheumatoid arthritis, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
- Patient must be aged 18 years or older.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.
- If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
- The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.
Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who...
has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate bDMARD (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the time of the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the
required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Ridley Park 8026
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) **How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.**

(a) **Initial treatment.**

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) **Continuing treatment.**

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Pricing subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before switching to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment. AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
### GOLIMUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

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(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction:

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

• Patient must have a documented history of active ankylosing spondylitis, AND
• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

GOLIMUBAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
• Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5
years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

**Within a Treatment Cycle** patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

1. **Initial treatment.**

   Applications for initial treatment should be made where:

   (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

   (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

   (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

   All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

   Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

   Grandfather patients - ustekinumab and secukinumab only.

   For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

   Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

2. **Continuing treatment.**

   Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

   Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

3. **Swapping therapy.**

   Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

   Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

   Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

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**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

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**GOLIMUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Active ankylosing spondylitis

Clinical criteria:
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

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• Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, AND
• Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND
• Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity that necessitates permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

If the application to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note: Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au.

Note: For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au.
no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure
uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required
Ankylosing spondylitis
Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply
Clinical criteria:
- Patient must have active, or a documented history of active, ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.
Population criteria:
- Patient must be an adult.
Treatment criteria:
- Must be treated by a rheumatologist.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe
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GOLIMUMAB
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Severe psoriatic arthritis
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
• Patient must have severe active psoriatic arthritis, AND
• Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
• Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
• Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
• Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
• Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

a) an active joint count of at least 20 active (swollen and tender) joints; or
b) at least 4 active joints from the following list of major joints:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
Note

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

Note

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '5(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify for initial biological treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 5 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

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golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

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**Interleukin inhibitors**

- **DACLIZUMAB**

  **Note** No increase in the maximum quantity or number of units may be authorised.

  **Note** No increase in the maximum number of repeats may be authorised.

  **Note** Special Pricing Arrangements apply.

**Authority required**
Multiple sclerosis

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**
- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

Patients should undergo monthly liver function testing while being treated with this drug.

**Authority required**
Multiple sclerosis

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**
• Must be treated by a neurologist.
Patients should undergo monthly liver function testing while being treated with this drug.

**Authority required**
Multiple sclerosis
Treatment Phase: Grandfathering treatment

**Clinical criteria:**
• The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
• The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient. **AND**
• Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years prior to initiation of this drug. **AND**
• Patient must have received treatment with this drug for this condition prior to 1 May 2017. **AND**
• The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
• Patient must be ambulatory (without assistance or support). **AND**
• The treatment must not exceed 24 weeks under this restriction.

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLACQUE PSORIASIS**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), when they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
General Pharmaceutical Benefits 485

Note
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Note
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1);
or
(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)
Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have been receiving treatment with this drug for this condition prior to 1 February 2017, AND
- Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug, AND
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (whole body), AND
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a dermatologist.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.
The most recent PASI assessment must be no more than 1 month old at the time of application.
A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note A PASI assessment of the patient’s response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a dermatologist.
For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.
Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Phase and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:
• Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
• Patient must have been receiving treatment with this drug for this condition prior to 1 February 2017, AND
• Patient must have had disease, prior to treatment with this drug, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, AND
• Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (face, hand, foot), AND
• Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.

Treatment criteria:
• Must be treated by a dermatologist.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 3, Whole body or Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment, Whole body or Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:
Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**IXEKIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukininab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukininab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle prior to 1 December 2007, to 1 December 2007. Patients receiving PBS-subsidised treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under (4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukininab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been...
demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
Department of Human Services
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction ‘biological agent’ means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.
The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:

• Patient must have a documented history of severe chronic plaque psoriasis, AND

• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

• Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

• The treatment must be as systemic monotherapy (other than methotrexate), AND

• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

• Patient must be aged 18 years or older.

Treatment criteria:

• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy,
will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required
Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
- For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
- The authority application must be made in writing and must include:
  (a) a completed authority prescription form; and
  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
  (ii) details of prior biological treatment, including dosage, date and duration of treatment.
- Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.
- An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
ANITNEOPLASTIC AND IMMUNOMODULATING AGENTS

Note A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 to discuss.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 to discuss.

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years ) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treament criteria:
• Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ixekizumab 80 mg/mL injection, 2 x 1 mL injection devices

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SECUKINUMAB

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required**

**Antineoplastic and immunomodulating agents**

**General**

**Complex Drugs**

Reply Paid 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

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**Secukinumab 150 mg/mL injection, 1 mL injection device**

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**Clinical criteria:**

- Patient must have active, or had a documented history of active ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the initial 1 or 2 restrictions.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

**Authority required**

**Severe psoriatic arthritis**

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete maximum of 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencing treatment after a break of less than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencing treatment after a break of less than 5 years) restriction to complete maximum of 16 weeks of treatment. AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

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**SECUKINUMAB**

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
- Department of Human Services
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- Reply Paid 9826
- HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of...
treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

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<td>Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply</td>
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Treatment criteria:
- Must be treated by a dermatologist.

**Secukinumab 150 mg/mL injection, 2 x 1 mL injection devices**

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**SECUKINUMAB**

*Note* Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial treatment – initial 1 (new patients or patients recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; **AND**
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
   (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
   (ii) a completed BASDAI Assessment Form; and
   (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
   (iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note For details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

### Authority required

**Ankylosing spondylitis**

**Treatment Phase: Initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)**

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

1. **How to prescribe PBS-subsidised bDMARD therapy**
   - (a) Initial treatment.
     - Applications for initial treatment should be made where:
       - (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
       - (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
       - (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

   A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

### secukinumab 150 mg/mL injection, 1 mL injection device

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**SECUKINUMB**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active psoriatic arthritis

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
**Population criteria:**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
- Patient must be aged 18 years or older.
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    1. elbow, wrist, knee, and/or ankle (assessed as swollen and tender); and/or
    2. shoulder, and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement; and
- (4) the date of commencement of this drug; and
- (5) results of the baseline patient assessment prior to commencing treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    1. elbow, wrist, knee, and/or ankle (assessed as swollen and tender); and/or
    2. shoulder, and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note: Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing
they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active psoriatic arthritis

Treatment Phase: Initial 3 (grandfather treatment) or Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfather patients) restriction to complete maximum of 24 weeks treatment, AND
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
secukinumab 150 mg/mL injection, 1 mL injection device

10895K

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 804.59 38.80 Cosentyx [NV]

- **SECUKINUMAB**

  - **Note** No increase in the maximum quantity or number of units may be authorised.
  - **Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active psoriatic arthritis

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months, **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement; and
4. the date of commencement of this drug; and
5. results of the baseline patient assessment prior to commencing treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

**Clinical criteria:**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note**
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment. Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active psoriatic arthritis
Treatment Phase: Initial 3 (grandfather treatment) or Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfather patients) restriction to complete maximum of 24 weeks treatment, AND
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

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SECUKINUMAB

Note The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
- Patient must have severe active psoriatic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years )
Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.
Population criteria:
• Patient must be aged 18 years or older.
Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.
Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.
An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the...
seukinumab 150 mg/mL injection, 2 x 1 mL injection devices

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**SECUKINUMAB**

**Note** The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Note: Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au).

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must arrange, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.
secukinumab 150 mg/mL injection, 1 mL injection device

10900Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---|---
4 | .. | .. | *3170.59 | 38.80 | Cosentyx [NV]

### SECUKINUMAB

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of

**Note** Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.
treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Within 12 weeks of approval for continuing treatment, patients may only swap to the alternate agent with the same biological class as prescribed for the initial treatment course. At the time of swapping, the PASI assessment must be conducted on the same affected area.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note: No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
• Patient must be aged 18 years or older.

**Treatment criteria:**
• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Note** A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Whole body or Face, hand, foot - balance of supply

**Clinical criteria:**
• Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND
• The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**
• Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
**SECUKINUMAB**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 3 (grandfather treatment)

**Clinical criteria:**

- Patient must have confirmed ankylosing spondylitis, defined radiographically (plain X-ray) of Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, with the diagnosis confirmed by a rheumatologist, AND
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2016, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The baseline BASDAI assessment must be from immediately prior to commencing treatment with this drug. The patient’s current BASDAI assessment and ESR and/or CRP measurements must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form; and
(c) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(d) a completed BASDAI Assessment Form; and
(e) a signed patient acknowledgment form;
(f) the date commencement of this drug;
(g) results of the baseline BASDAI assessment prior to commencing treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

Note The assessment of the patient’s response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Antineoplastic and immunomodulating agents

General

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Antineoplastic and immunomodulating agents

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-
  rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same
marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of
therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the
application is the first application for continuing treatment following an initial treatment course it must be made following a
minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the
patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive
further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5
years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and
the date of the first application under a new cycle.

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab,
certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept,
golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term

- treatment with a bDMARD while they continue to show a response to therapy.
- Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD
  more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment
cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to
commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD
treatment in the most recent cycle to the date of the first application for continuing treatment following an initial treatment

- therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.
- Where a response assessment is not submitted to the Department of Human Services within these timeframes, the
  patient will be deemed to have failed this course of treatment.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years
may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years
may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

- Applications for initial treatment should be made where:
  - a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such
    therapy (Initial 1); or
  - a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent
    (Initial 2) [further details are under ‘Swapping therapy’ below]; or
  - a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with
    that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5
    years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks
of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the
date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient
will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in
the month prior to completing their current course of treatment and that an application is posted to the Department of Human
Services no later than 2 weeks prior to the patient completing their current treatment course.

- Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications

for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction (c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis
Treatment Phase: Initial 3 or Continuing treatment – balance of supply

Clinical criteria:
• Patient must have a documented history of active ankylosing spondylitis, AND
• Patient must have received insufficient therapy with this drug under the initial 3 treatment restriction to complete 24 weeks of treatment, AND
• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
**SEUCKINUMAB**

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**

- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**
• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

**Severe chronic plaque psoriasis**

**Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)**

**Clinical criteria:**
- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.
secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

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Authority required

TOCILIZUMAB

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatmen criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
1. completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note: No increase in the maximum number of repeats may be authorised.

Note: No increase in the maximum quantity or number of units may be authorised.

### Authority required

**Severe active rheumatoid arthritis**

**Treatment Phase: Continuing treatment – balance of supply**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note: Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).**

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

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### TOCILIZUMAB

**Note: No increase in the maximum number of repeats may be authorised.**

**Note: No increase in the maximum quantity or number of units may be authorised.**

### Authority required

**Severe active rheumatoid arthritis**

**Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after break of more than 24 months)**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must have not failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond, to PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis initial PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes: (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed
treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:(a) completed authority prescription form(s); and(b) a completed Rheumatoid Arthritis continuing PBS Authority Application - Supporting Information Form. Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:

**Notes:**
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD while without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity
of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to resubmit with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that bDMARD.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Rituximab patients:
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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### USTEKINUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### Treatments of Adult Patients with Severe Chronic Plaque Psoriasis

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis:

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '4 (Swapping therapy) below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
For the purposes of this restriction ‘biological agent’ means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

**Notes**
- A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
- In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
- Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
- It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

### Authority required

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Face, hand, foot

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.
General

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:
- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Usteekinumab 45 mg/0.5 mL injection, 0.5 mL vial

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### USTEKINUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years.
years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Severe psoriatic arthritis**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** **TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy. Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

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<td>Severe psoriatic arthritis</td>
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Treatment Phase: Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

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**USTEKINUMAB**

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have severe active psoriatic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
- If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
- The authority application must be made in writing and must include:
  - (1) a completed authority prescription form; and
  - (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
  - (3) a signed patient acknowledgement.

Note: Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au).

Note: The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note: Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive the assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased. Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment. An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note: The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note: Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note: Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

1. Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more), Initial 2 (change or recommencement of treatment) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 28 weeks treatment. **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

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**USTEKINUMAB**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:
- (i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or
- (iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) (further details are under ‘(4) Swapping therapy’ below); or
(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.
• Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
• Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.

Treatment criteria:
• Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:
• Patient must have a documented history of severe chronic plaque psoriasis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
**General**

**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
- a completed authority prescription form; and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:
- A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

**Note:** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note:** Patients who fail to demonstrate a response to PBS-subsidised treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note:** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy,
will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

### Authority required

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

#### Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

#### Treatment criteria:

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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### USTEKINUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1 kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy. A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial...
treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle. A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab. From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 40 mg with 3 repeats. Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy. A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD...
therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

(6) Patients ‘grandfathered’ onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

**Authority required**

**Severe Crohn disease**

**Treatment Phase: Initial treatment (new patient - initial 1)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician (general medicine specialising in gastroenterology (code 81)); OR
- Must be treated by a consultant physician (gastroenterology (code 82)).

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
Note: It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note: Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Note: No increase in the maximum number of repeats may be authorised.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, AND
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.
- Applications for authorisation must be made in writing and must include:
  - (a) two completed authority prescription forms; and
  - (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
    - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
    - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
    - (iii) the date of clinical assessment; and
  - (iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4
vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe Crohn disease
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have a documented history of severe Crohn disease, AND
• Patient must have previously been issued with an authority prescription for this drug for this condition, AND
• Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND
• Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
• Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or an ostomy patient.

Population criteria:
• Patient must be aged 18 years or older.

Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.
The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe Crohn disease

**Treatment Phase:** Initial PBS-subsidised treatment (Grandfather)

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2017, **AND**
- Patient must be receiving treatment with ustekinumab at the time of application, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease Grandfathered PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iv) the date of the most recent clinical assessment; and
(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.
The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note No applications for increased maximum quantities will be authorised.

Note Increase in the maximum number of repeats of up to two may be authorised in patients whose dosing frequency is every 8 weeks.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe Crohn disease
Treatment Phase: Balance of supply for Initial treatment, Continuing treatment or Grandfathered treatment

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 16 weeks of treatment; OR
• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
• Patient must have received insufficient therapy with this drug under the Grandfathered treatment restriction to complete 24 weeks of treatment.

Population criteria:
• Patient must be aged 18 years or older.

Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authority to prescribe may be made by phone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

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Calcineurin inhibitors

CYCLOSPORIN
Caution Careful monitoring of patients is mandatory.

cyclosporin 50 mg capsule, 30

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cyclosporin 10 mg capsule, 60

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cyclosporin 100 mg capsule, 30
8660T
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
2 3 .. *308.81 38.80 * Cyclosporin Sandoz [SZ] * Neoral 100 [NV]

cyclosporin 25 mg capsule, 30
8658Q
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
2 3 .. *80.37 38.80 * Cyclosporin Sandoz [SZ] * Neoral 25 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL
8661W
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
2 3 .. *707.63 38.80 Neoral [NV]

■ TACROLIMUS
Caution Careful monitoring of patients is mandatory.
tacrolimus 2 mg capsule, 100
10871E
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 3 .. 561.21 38.80 Tacrolimus Sandoz [SZ]

tacrolimus 1 mg modified release capsule, 60
5300Y
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 3 .. 152.63 38.80 * ADVAGRAF XL [LQ] * Prograf XL [LL]

tacrolimus 1 mg capsule, 100
8647D
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

tacrolimus 5 mg modified release capsule, 30
5451X
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 3 .. 422.35 38.80 * ADVAGRAF XL [LQ] * Prograf XL [LL]

tacrolimus 5 mg capsule, 50
8648E
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

tacrolimus 750 microgram capsule, 100
10870D
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 3 .. 213.45 38.80 Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule, 100
8646C
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 3 .. 129.04 38.80 * Pacrolim [AF] * Prograf [LL] * Pharmacor Tacrolimus 0.5 [CR] * TACROLIMUS APOTEX [TX] * Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram modified release capsule, 30
5299X
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 3 .. 51.43 38.80 * ADVAGRAF XL [LQ] * Prograf XL [LL]

Other immunosuppressants

■ AZATHIOPRINE
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
azathioprine 50 mg tablet, 100
2687K
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
METHOTREXATE

methotrexate 2.5 mg tablet, 30

methotrexate 10 mg tablet, 15

METHOTREXATE

Restricted benefit
Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

PIRFENIDONE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Idiopathic pulmonary fibrosis
Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:
- The condition must be diagnosed through a multidisciplinary team, AND
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, AND
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, AND
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, AND
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, AND
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, AND
- The treatment must be the sole PBS-subsidised treatment for this condition.

Treatment criteria:
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

Applications for authorisation of initial treatment must be in writing and must include:
- a completed authority prescription form; and
- a completed IPF Authority Application Supporting Information Form; and
- a signed patient acknowledgement.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Idiopathic pulmonary fibrosis
Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**

**Treatment criteria:**
• Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

---

**Authority required**

Idiopathic pulmonary fibrosis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

**Treatment criteria:**
• Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Idiopathic pulmonary fibrosis

**Treatment Phase: Initial treatment 3 - Grandfathering treatment**

**Clinical criteria:**
• Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2017, **AND**

• The condition must have been diagnosed through a multidisciplinary team, **AND**

• Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**

• Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**

• Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**

• Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**

• The treatment must be the sole PBS-subsidised treatment for this condition.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must have not have an acute respiratory infection at the time of FVC testing.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or change or recommencement of treatment criteria.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Applications for authorisation of initial treatment must be in writing and must include:

a) a completed authority prescription form; and

b) a completed IPF Authority Application Supporting Information Form; and

c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**pirfenidone 267 mg capsule, 270**

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MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Acetic acid derivatives and related substances

**DICLOFENAC**

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**DICLOFENAC**

Restricted benefit
Chronic arthropathies (including osteoarthritis)
Clinical criteria:
- The condition must have an inflammatory component.

**Bone pain**
Clinical criteria:
- The condition must be due to malignant disease.

**DICLOFENAC**

**diclofenac sodium 100 mg suppository**, 20

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**diclofenac sodium 25 mg enteric tablet**, 50

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**diclofenac sodium 50 mg enteric tablet**, 50

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**Indomethacin 100 mg suppository, 20**

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**Indomethacin 100 mg suppository, 20**

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**Indomethacin 25 mg capsule, 50**

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### MELOXICAM

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**Meloxicam 7.5 mg capsule, 30**

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**Oxicams**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**
- The condition must be due to malignant disease.

**Restricted benefit**

**Osteoarthritis**

**Clinical criteria:**
- Patient must be symptomatic.

**Restricted benefit**

**Rheumatoid arthritis**

**Clinical criteria:**
- Patient must be symptomatic.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.
### Meloxicam 7.5 mg Tablet, 30

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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>13.89</td>
<td>15.10</td>
<td>* APO-Meloxicam [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Meloxicam 7.5 [DO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Meloxicam AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Meloxicam Ranbaxy [RA]</td>
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<td></td>
<td></td>
<td>* Movals 7.5 [RW]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>* Pharmacor Meloxicam 7.5 [CR]</td>
</tr>
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</table>

**PIROXICAM**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

### Piroxicam 20 mg Dispersible Tablet, 25

<table>
<thead>
<tr>
<th>1896T</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>15.87</td>
<td>17.08</td>
<td>* Mobilis D-20 [AF]</td>
</tr>
</tbody>
</table>

### Piroxicam 20 mg Dispersible Tablet, 25

<table>
<thead>
<tr>
<th>5201R</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>DP</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>15.87</td>
<td>17.08</td>
<td>* Mobilis D-20 [AF]</td>
</tr>
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</table>

### Piroxicam 20 mg Capsule, 25

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>15.87</td>
<td>17.08</td>
<td>* GenRx Piroxicam [GX]</td>
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</table>

### Piroxicam 20 mg Capsule, 25

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>DP</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>15.87</td>
<td>17.08</td>
<td>* GenRx Piroxicam [GX]</td>
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</table>

### Piroxicam 10 mg Dispersible Tablet, 50

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>16.12</td>
<td>17.33</td>
<td>Mobilis D-10 [AF]</td>
</tr>
</tbody>
</table>

### Piroxicam 10 mg Dispersible Tablet, 50

<table>
<thead>
<tr>
<th>5201R</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>..</td>
<td>..</td>
<td>16.12</td>
<td>17.33</td>
<td>Mobilis D-10 [AF]</td>
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### Propionic acid derivatives

#### IBUPROFEN

**ibuprofen 400 mg tablet, 30**

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<thead>
<tr>
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<td>3190B</td>
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<td>Brufen [GO]</td>
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**ibuprofen 400 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>5124Q</td>
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<td>APO-Ibuprofen 400 [TX]</td>
<td>Brufen [GO]</td>
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</tbody>
</table>

**IBUPROFEN**

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:
- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

<table>
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<tr>
<th>Max Qty Packs</th>
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**IBUPROFEN**

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Chronic arthropathies (including osteoarthritis)

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**ibuprofen 400 mg tablet, 30**

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<td>APO-Ibuprofen 400 [TX]</td>
<td>Brufen [GO]</td>
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</table>

**KETOPROFEN**

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component.

**ketoprofen 200 mg modified release capsule, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>1590Q</td>
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<td>* Oruvail SR [AV]</td>
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**ketoprofen 200 mg modified release capsule, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>5136H</td>
<td></td>
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<td>* Oruvail SR [AV]</td>
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</table>

**NAPROXEN**

Restricted benefit
Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:
- The condition must be due to malignant disease.

naproxen 250 mg tablet, 50

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Inza 250 [AF]</td>
<td>2</td>
<td>3</td>
<td>18.35</td>
<td>19.56</td>
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</tr>
<tr>
<td>Naprosyn [IX]</td>
<td>2</td>
<td>3</td>
<td>20.59</td>
<td>19.56</td>
<td>a</td>
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</table>

naproxen 750 mg modified release tablet, 28

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inza 500 [AF]</td>
<td>1</td>
<td>3</td>
<td>16.01</td>
<td>17.22</td>
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</tr>
<tr>
<td>Naprosyn SR750 [IX]</td>
<td>1</td>
<td>3</td>
<td>17.07</td>
<td>17.22</td>
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naproxen 500 mg tablet, 50

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inza 500 [AF]</td>
<td>1</td>
<td>3</td>
<td>16.46</td>
<td>17.67</td>
<td>a</td>
</tr>
<tr>
<td>Naprosyn [IX]</td>
<td>1</td>
<td>3</td>
<td>17.58</td>
<td>17.67</td>
<td>a</td>
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</table>

naproxen 1 g modified release tablet, 28

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inza 1000 [IX]</td>
<td>1</td>
<td>3</td>
<td>17.65</td>
<td>18.86</td>
<td>a</td>
</tr>
<tr>
<td>Naprosyn SR1000 [IX]</td>
<td>1</td>
<td>3</td>
<td>18.77</td>
<td>18.86</td>
<td>a</td>
</tr>
</tbody>
</table>

NAPROXEN

Authority required (STREAMLINED)

4159
Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component, AND
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

Authority required (STREAMLINED)

4124
Bone pain

Clinical criteria:
- The condition must be due to malignant disease, AND
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

naproxen 125 mg/5 mL oral liquid, 474 mL

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>Phebra Naproxen Suspension</td>
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<td>121.27</td>
<td>38.80</td>
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</tr>
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</table>

NAPROXEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:
- The condition must be due to malignant disease.
### MUSCULO-SKELETAL SYSTEM

### General Pharmaceutical Benefits

#### Naproxen 500 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>16.46</td>
<td>17.67</td>
<td>* Inza 500 [AF]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.12</td>
<td>17.58</td>
<td>17.67</td>
<td>* Naprosyn [IX]</td>
</tr>
</tbody>
</table>

#### Naproxen 1 g modified release tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>17.65</td>
<td>18.86</td>
<td>* Proxen SR 1000 [IY]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>1.12</td>
<td>18.77</td>
<td>18.86</td>
<td>* Naprosyn SR1000 [IX]</td>
</tr>
</tbody>
</table>

#### NAPROXEN

**Note:** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**
- The condition must be due to malignant disease.

#### Naproxen sodium 550 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>16.61</td>
<td>17.82</td>
<td>* Crysanal [IY]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>1.89</td>
<td>18.50</td>
<td>17.82</td>
<td>* Anaprox 550 [IX]</td>
</tr>
</tbody>
</table>

#### NAPROXEN

**Note:** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**
- The condition must be due to malignant disease.

#### Naproxen sodium 550 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>1.89</td>
<td>18.50</td>
<td>17.82</td>
<td>* Anaprox 550 [IX]</td>
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</tbody>
</table>

### Fenamates

#### MEFENAMIC ACID

**Restricted benefit**

Dysmenorrhoea

**Restricted benefit**

Menorrhagia

#### Mefenamic acid 250 mg capsule, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
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</table>

### Coxibs

#### CELECOXIB

**Note:** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

**Restricted benefit**

Osteoarthritis

**Clinical criteria:**
- The treatment must be for symptomatic treatment.

**Restricted benefit**

Rheumatoid arthritis

**Clinical criteria:**
MUSCULO-SKELETAL SYSTEM

- The treatment must be for symptomatic treatment.

### Celecoxib 100 mg capsule, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>* APO-Celecoxib [TX]</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>18.03</td>
<td>19.24</td>
</tr>
<tr>
<td>* Blooms the Chemist Celecoxib [IB]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Celebrex [PF]</td>
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</tr>
<tr>
<td>* Celecoxib GH [GQ]</td>
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<tr>
<td>* Celecoxib Sandoz [SZ]</td>
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<tr>
<td>* Chem mart Celecoxib [CH]</td>
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<tr>
<td>* Celaxib [AF]</td>
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<tr>
<td>* Celecoxib RBX [RA]</td>
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<tr>
<td>* Celexi [RW]</td>
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<tr>
<td>* Terry White Chemists Celecoxib [TW]</td>
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### Celecoxib 200 mg capsule, 30

<table>
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<th>Brand Name and Manufacturer</th>
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<td>19.24</td>
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<td>* Blooms the Chemist Celecoxib [IB]</td>
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<tr>
<td>* Celebrex [PF]</td>
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<tr>
<td>* Celecoxib GH [GQ]</td>
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<tr>
<td>* Celecoxib Sandoz [SZ]</td>
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<td>* Chem mart Celecoxib [CH]</td>
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<td>* Celecoxib RBX [RA]</td>
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<tr>
<td>* Celexi [RW]</td>
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<td>* Terry White Chemists Celecoxib [TW]</td>
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SPECIFIC ANTIRHEUMATIC AGENTS

#### Quinolines

- **Hydroxychloroquine**
  - **Note Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
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<th>MRVSN $</th>
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<td>* Hydroxychloroquine AN [EA]</td>
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<td></td>
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</tr>
<tr>
<td>* Hydroxychloroquine GH [GQ]</td>
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<td></td>
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<tr>
<td>* Plaquenil [SW]</td>
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<td>* Hequinel [RW]</td>
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</tbody>
</table>

Gold preparations

- **Auranofin**
  - **Caution** Regular blood and urine checks are essential.
  - **Note Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Auranofin 3 mg tablet, 60

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### Auranofin 3 mg capsule, 60

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- **Sodium Aurothiomalate**
  - **Caution** Regular blood and urine checks are essential.
  - **Note Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### MUSCULO-SKELETAL SYSTEM

**SODIUM AUROTHIOMALATE 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

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<th>2017E</th>
<th>Max Qty Packs</th>
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<td>113.23</td>
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**SODIUM AUROTHIOMALATE 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

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<td>137.22</td>
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**SODIUM AUROTHIOMALATE 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules**

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<tr>
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<td>77.48</td>
<td>38.80</td>
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<td>Myocrisin [SW]</td>
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**Penicillamine and similar agents**

**PENICILLAMINE**

Caution: Regular blood and urine checks are essential.

Note: Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Penicillamine 125 mg tablet, 100**

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<tr>
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<td>45.17</td>
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**Penicillamine 250 mg tablet, 100**

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<td>D-Penamine [AL]</td>
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**MUSCLE RELAXANTS**

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

**Other centrally acting agents**

**BACLOFEN**

**Baclofen 10 mg tablet, 100**

<table>
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<tr>
<th>2729P</th>
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<td>1</td>
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<tr>
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<td></td>
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<td></td>
<td>Clofen 10 [AF]</td>
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<td></td>
<td>Lioresal 10 [NV]</td>
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<td></td>
<td></td>
<td>Chem mart Baclofen [CH]</td>
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<td></td>
<td>GenRx Baclofen [GX]</td>
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<td>Stelax 10 [RW]</td>
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**Baclofen 25 mg tablet, 100**

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<td>Clofen 25 [AF]</td>
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<td>Lioresal 25 [NV]</td>
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<td>GenRx Baclofen [GX]</td>
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<td>Stelax 25 [RW]</td>
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**MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS**

**Dantrolene and derivatives**

**DANTROLENE**

Restricted benefit

**Dantrolene sodium 50 mg capsule, 100**

<table>
<thead>
<tr>
<th>1780Q</th>
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**Dantrolene sodium 25 mg capsule, 100**

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<td>75.67</td>
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</table>
MUSCULO-SKELETAL SYSTEM

ANTIGOUT PREPARATIONS

Preparations inhibiting uric acid production

ALLOPURINOL

Note The dose should be adjusted in accordance with renal function.

allopurinol 300 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Allopurinol [TX]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>* Progout 300 [AF]</td>
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<tr>
<td></td>
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<td>3.48</td>
<td>18.09</td>
<td>* Allosig [RF]</td>
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<td></td>
<td></td>
<td>* Chem mart Allopurinol [CH]</td>
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<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists</td>
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</tr>
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<td>Allopurinol [TW]</td>
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ALLOPURINOL

Note The dose should be adjusted in accordance with renal function.

Note For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

allopurinol 100 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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allopurinol 100 mg tablet, 200

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<td>* APO-Allopurinol [TX]</td>
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<td>* Progout 100 [AF]</td>
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<td>* Chem mart Allopurinol [CH]</td>
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<td>* Terry White Chemists</td>
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<td></td>
<td></td>
<td></td>
<td>Allopurinol [TW]</td>
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</table>

FEBUXOSTAT

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Chronic gout
Clinical criteria:
- The condition must be either chronic gouty arthritis or chronic tophaceous gout, AND
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

febuxostat 80 mg tablet, 28

<table>
<thead>
<tr>
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PROBENECID

probencid 500 mg tablet, 100

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<th>DPMQ $</th>
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COLCHICINE

colchicine 500 microgram tablet, 30

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<td></td>
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<td>2.90</td>
<td>17.97</td>
<td>* Colgout [AS]</td>
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MUSCULO-SKELETAL SYSTEM

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

▪ ALENDRONATE

Restricted benefit
Corticosteroid-induced osteoporosis

Clinical criteria:
• Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND
• Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit
Osteoporosis

Population criteria:
• Patient must be aged 70 years or older.

Clinical criteria:
• Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit
Established osteoporosis

Clinical criteria:
• Patient must have fracture due to minimal trauma, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

alendronate 70 mg tablet, 4

<table>
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<td>..</td>
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<td>16.21</td>
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<td>Alendronate Sandoz [SZ]</td>
<td>Alendro Once Weekly [RW]</td>
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<td>Densate 70 [DO]</td>
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▪ CLODRONATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Hypercalcaemia of malignancy

Clinical criteria:
• Patient must have a malignancy refractory to anti-neoplastic therapy.

Restricted benefit
Multiple myeloma

Restricted benefit
Bone metastases

Clinical criteria:
• The condition must be due to breast cancer.
clodronate sodium 400 mg capsule, 100
8132B
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 .. 309.26 38.80 Bonefos [BN]

clodronate sodium 800 mg tablet, 60
8265B
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 .. 365.66 38.80 Bonefos 800 mg [BN]

IBANDRONATE
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Bone metastases
Clinical criteria:
• The condition must be due to breast cancer.

ibandronate 50 mg tablet, 28
9357L
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 .. 317.38 38.80 Bondronat [RO]

PAMIDRONATE DISODIUM
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Symptomatic Paget disease of bone

pamidronate disodium 15 mg/5 mL injection, 5 mL vial
8461H
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
4 .. .. *70.51 38.80 Pamisol [PF]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial
8462J
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 .. .. *70.51 38.80 Pamisol [PF]

pamidronate disodium 60 mg/10 mL injection, 10 mL vial
8463K
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 70.51 38.80 Pamisol [PF]

RISEDRONATE
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Symptomatic Paget disease of bone

risedronate sodium 30 mg tablet, 28
8482K
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. 175.09 38.80 Actonel [UA]

RISEDRONATE
Restricted benefit
Corticosteroid-induced osteoporosis
Clinical criteria:
• Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND
• Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.
MUSCULO-SKELETAL SYSTEM

Restricted benefit
Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit
Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**ZOLEDRONIC ACID**

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

5710
Symptomatic Paget disease of bone
Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 100 mL bag**

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**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

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<td>370.31</td>
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</tr>
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</table>

**ZOLEDRONIC ACID**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**
Corticosteroid-induced osteoporosis

Clinical criteria:
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

Osteoporosis

Population criteria:
- Patient must be aged 70 years or older.

Clinical criteria:
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,
- Patient must not receive more than one PBS-subsidised treatment per year.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

Established osteoporosis

Clinical criteria:
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

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**Bisphosphonates, combinations**

- **ALENDRONATE + COLECALCIFEROL**

  Note: Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

Corticosteroid-induced osteoporosis

Clinical criteria:
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

Osteoporosis

Population criteria:
- Patient must be aged 70 years or older.

Clinical criteria:
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6319**
Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### alendronate 70 mg + colecalciferol 140 microgram tablet, 4

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### ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**Authority required (STREAMLINED)**

**6307**
Corticosteroid-induced osteoporosis

**Clinical criteria:**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6320**
Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6315**
Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### alendronate 70 mg + colecalciferol 70 microgram tablet, 4

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### ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

6306  
Corticosteroid-induced osteoporosis  
**Clinical criteria:**  
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**  
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**  
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.  

**Authority required (STREAMLINED)**

6325  
Osteoporosis  
**Population criteria:**  
- Patient must be aged 70 years or older.  
**Clinical criteria:**  
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**  
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.  

**Authority required (STREAMLINED)**

6319  
Established osteoporosis  
**Clinical criteria:**  
- Patient must have fracture due to minimal trauma, **AND**  
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

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<td>* Dronalen Plus D-Cal [AF]</td>
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<td>* Fosamax Plus [MK]</td>
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**RISEDRONATE (&) CALCIUM CARBONATE**  
**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

6306  
Corticosteroid-induced osteoporosis  
**Clinical criteria:**  
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**  
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**  
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.  

**Authority required (STREAMLINED)**

6325  
Osteoporosis  
**Population criteria:**  
- Patient must be aged 70 years or older.  
**Clinical criteria:**  
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319
Established osteoporosis

Clinical criteria:
• Patient must have fracture due to minimal trauma, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

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risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

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*RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL*

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306
Corticosteroid-induced osteoporosis

Clinical criteria:
• Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND
• Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325
Osteoporosis

Population criteria:
• Patient must be aged 70 years or older.

Clinical criteria:
• Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319
Established osteoporosis

Clinical criteria:
• Patient must have fracture due to minimal trauma, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

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Other drugs affecting bone structure and mineralization
CALCITRIOL

**Authority required (STREAMLINED)**

**5401**

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

**5255**

Hypoparathyroidism

**Authority required (STREAMLINED)**

**5089**

Hypophosphataemic rickets

**Authority required (STREAMLINED)**

**5114**

Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

**5402**

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma.
- The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Calcitriol 0.25 microgram capsule, 100**

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DENOSUMAB

**Note**

Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4504**

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

**Denosumab 120 mg/1.7 mL injection, 1.7 mL vial**

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DENOSUMAB

**Note**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4158**

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Authority required (STREAMLINED)**

**4150**

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.
**DENOSUMAB**

Note: Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

**6548**

Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**6524**

Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**RALOXIFENE**

Note: Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

**6314**

Established post-menopausal osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**TERIPARATIDE**

Note: No increase in the maximum quantity or number of units may be authorised.

**Authority required**

Severe established osteoporosis

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

**Clinical criteria:**
- Patient must be at very high risk of fracture, AND
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, AND

---

**General Pharmaceutical Benefits**

4110Y

General denosumab 120 mg/1.7 mL injection, 1.7 mL vial

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**5110Y**

General denosumab 120 mg/mL injection, 1 mL syringe

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**5457F**

General denosumab 60 mg/mL injection, 1 mL syringe

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**8363E**

General raloxifene hydrochloride 60 mg tablet, 28

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<td>Raloxifene AMNEAL [ED]</td>
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</table>
• Patient must have had 2 or more fractures due to minimal trauma, **AND**
• Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
• The treatment must be the sole PBS-subsidised agent, **AND**
• The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note** Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

### Authority required

Severe established osteoporosis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

• Patient must have previously been issued with an authority prescription for this drug, **AND**
• The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

### teriparatide 20 microgram injection, 2.4 mL cartridge

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### NERVOUS SYSTEM

### ANALGESICS

#### Codeine

**Codeine phosphate 30 mg tablet, 20**

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**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

### Codeine

**Codeine phosphate 30 mg tablet, 20**

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### Hydromorphone

**Caution** The risk of drug dependence is high.

**Hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules**

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**Hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

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- **HYDROMORPHONE**
  
  **Caution** The risk of drug dependence is high.

  **Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

  **Restricted benefit**
  
  **Severe disabling pain**
  
  **Clinical criteria:**
  
  - The condition must be unresponsive to non-opioid analgesics.

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- **HYDROMORPHONE**
  
  **Caution** The risk of drug dependence is high.

  **Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
  
  (i) chronic severe disabling pain associated with proven malignant neoplasia; or
  
  (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
  
  (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
  
  (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

  **Restricted benefit**
  
  **Severe disabling pain**
  
  **Clinical criteria:**
  
  - The condition must be unresponsive to non-opioid analgesics.
must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

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<th>Restricted benefit</th>
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<td>• The condition must be unresponsive to non-opioid analgesics.</td>
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### hydromorphone hydrochloride 64 mg modified release tablet, 14

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### MORPHINE

**Caution** The risk of drug dependence is high.

### morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules

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### morphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

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### morphine hydrochloride 100 mg/5 mL injection, 5 x 5 mL ampoules

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### morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules

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### morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules

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### morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules

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<td>42.74</td>
<td>38.80</td>
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</table>

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

### morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>5170D</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>25.13</td>
<td>Hospira Pty Limited [PF]</td>
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</table>
MORPHINE

Caution: The risk of drug dependence is high.

Note: Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

MORPHINE

Caution: The risk of drug dependence is high.

Authority required

Clinical criteria:
- The condition must be due to cancer, AND
- The condition must be unresponsive to non-opioid analgesics.

MORPHINE

Caution: The risk of drug dependence is high.

Restricted benefit

Clinical criteria:
- The condition must be due to cancer, AND
- The condition must be unresponsive to non-opioid analgesics.

MORPHINE

Caution: The risk of drug dependence is high.

Note: Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note: Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.
morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Hospira Pty Limited [PF]</td>
</tr>
</tbody>
</table>

**MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 30 mg tablet, 20**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>Anamorph [RW]</td>
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**morphine hydrochloride 10 mg/mL oral liquid, 200 mL**

<table>
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</thead>
<tbody>
<tr>
<td>Ordine 10 [MF]</td>
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</tbody>
</table>

**morphine hydrochloride 5 mg/mL oral liquid, 200 mL**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Ordine 5 [MF]</td>
</tr>
</tbody>
</table>

**morphine hydrochloride 2 mg/mL oral liquid, 200 mL**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Ordine 2 [MF]</td>
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</table>

**MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

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(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate 10 mg modified release tablet, 28**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<td>Momex SR 10 [RW]</td>
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**morphine sulfate 30 mg modified release capsule, 14**

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<td>MS Mono [MF]</td>
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<td>Brand Name and Manufacturer</td>
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<tr>
<td>----------------------------</td>
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<tr>
<td>morphine sulfate 15 mg modified release tablet, 28</td>
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<tr>
<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 90 mg modified release capsule, 14</td>
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<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>morphine Capsule 50 mg (containing sustained release pellets), 28</td>
</tr>
<tr>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>morphine sulfate 5 mg modified release tablet, 28</td>
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<tr>
<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 120 mg modified release capsule, 14</td>
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<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 30 mg modified release tablet, 28</td>
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<tr>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>morphine Capsule 100 mg (containing sustained release pellets), 28</td>
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<tr>
<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 100 mg modified release tablet, 28</td>
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<tr>
<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 100 mg modified release granules, 28 sachets</td>
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<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 60 mg modified release tablet, 28</td>
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<td>Brand Name and Manufacturer</td>
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<td>morphine Capsule 20 mg (containing sustained release pellets), 28</td>
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<td>Brand Name and Manufacturer</td>
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<tr>
<td>morphine sulfate 20 mg modified release granules, 28 sachets</td>
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<tr>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>morphine Capsule 10 mg (containing sustained release pellets), 28</td>
</tr>
<tr>
<td>Brand Name and Manufacturer</td>
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</table>
**NERVOUS SYSTEM**

**Morphine**

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

### Restricted benefit

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

**Morphine sulfate 30 mg tablet, 20**

### Morphine hydrochloride 10 mg/mL oral liquid, 200 mL

### Morphine hydrochloride 5 mg/mL oral liquid, 200 mL

### Morphine hydrochloride 2 mg/mL oral liquid, 200 mL

**Oxycodone**

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

### Oxycodone hydrochloride 10 mg capsule, 20

### Oxycodone hydrochloride 5 mg tablet, 20

### Oxycodone hydrochloride 5 mg capsule, 20
**NERVOUS SYSTEM**

**OXYCODONE**

Caution: The risk of drug dependence is high.

Note: Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

### Restricted benefit

- The condition must be unresponsive to non-opioid analgesics.

### Clinical criteria:

#### oxycodone hydrochloride 10 mg capsule, 20

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Endone [QA]</td>
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<tr>
<td>Proladone [PL]</td>
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#### oxycodone hydrochloride 5 mg tablet, 20

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>Endone [QA]</td>
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<tr>
<td>Proladone [PL]</td>
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#### oxycodone hydrochloride 5 mg capsule, 20

<table>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Endone [QA]</td>
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<tr>
<td>Proladone [PL]</td>
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#### oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

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## OXYCODONE

Caution: The risk of drug dependence is high.

### Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note: OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

### Restricted benefit

- Chronic severe disabling pain

#### Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.
oxycodone hydrochloride 40 mg modified release tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td></td>
<td>OxyContin [MF]</td>
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</table>

- Novacodone [HX]
- OxyContin [MF]
- Oxycodone Sandoz [SZ]

oxycodone hydrochloride 10 mg modified release tablet, 28

<table>
<thead>
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<th>Max Qty Packs</th>
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<td>OxyContin [MF]</td>
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</tbody>
</table>

- Novacodone [HX]
- OxyContin [MF]
- Oxycodone Sandoz [SZ]

oxycodone hydrochloride 80 mg modified release tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td></td>
<td></td>
<td>OxyContin [MF]</td>
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</tbody>
</table>

- Novacodone [HX]
- OxyContin [MF]
- Oxycodone Sandoz [SZ]

### OXYCODONE

Caution

- The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

- **Restricted benefit**
  - Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 30 mg modified release tablet, 28

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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oxycodone hydrochloride 15 mg modified release tablet, 28

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<td>OxyContin [MF]</td>
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</tbody>
</table>

### OXYCODONE + NALOXONE

Caution

- The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

- **Restricted benefit**
  - Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28

<table>
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<tr>
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- Targin 2.5/1.25 mg [MF]
oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28

8936H
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 72.42 38.80 Targin 40/20mg [MF]

oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28

10757E
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 37.18 38.39 Targin 15/7.5mg [MF]

oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28

8935G
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 47.32 38.80 Targin 20/10mg [MF]

oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28

11102H
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 79.72 38.80 Targin 60/30 [MF]

oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28

10758F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 53.47 38.80 Targin 30/15 mg [MF]

oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28

8000C
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 31.70 32.91 Targin 5/2.5mg [MF]

oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28

11111T
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 94.36 38.80 Targin 80/40 [MF]

oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28

8934F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 32.83 34.04 Targin 10/5mg [MF]

Phenylpiperidine derivatives

FENTANYL

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
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(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

Restricted benefit
Chronic severe disabling pain

Clinical criteria:
- The condition must be unresponsive to non-opioid analgesics.

Fentanyl 50 microgram/hour patch, 5

5278T
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 33.88 35.09 * Denpax [AF]
### NERVOUS SYSTEM

**fentanyl 50 microgram/hour patch, 5**

<table>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
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<tr>
<td>1</td>
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<td>* Fenpatch 50 [ZP]</td>
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**fentanyl 50 microgram/hour patch, 5**

<table>
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<tr>
<td>1</td>
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<td>35.09</td>
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<td>* APO-Fentanyl [TX]</td>
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<td></td>
<td>* Fentanyl Sandoz [SZ]</td>
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<td>* Durogesic 50 [JC]</td>
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**fentanyl 25 microgram/hour patch, 5**

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
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<td>* Fenpatch 25 [ZP]</td>
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**fentanyl 25 microgram/hour patch, 5**

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<td>24.86</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>* Fentanyl Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Durogesic 25 [JC]</td>
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**fentanyl 12 microgram/hour patch, 5**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
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<td></td>
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<td>* Dutran 12 [EA]</td>
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<td>* Fenpatch 12 [ZP]</td>
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**fentanyl 12 microgram/hour patch, 5**

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<tr>
<th>Max Qty Packs</th>
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<td>* Durogesic 12 [JC]</td>
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**fentanyl 100 microgram/hour patch, 5**

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<tbody>
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**fentanyl 75 microgram/hour patch, 5**

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<td>* Fentanyl Sandoz [SZ]</td>
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<td>* Durogesic 75 [JC]</td>
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**Diphenylpropylamine derivatives**

- **METHADONE**
  
  **Caution** The risk of drug dependence is high.
  
  **Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
  
  (i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

- The condition must be unresponsive to non-opioid analgesics.

### Methadone hydrochloride 10 mg tablet, 20

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<tr>
<th>Max Qty Packs</th>
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### Methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

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<thead>
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</table>

### Oripavine derivatives

- **BUPRENORPHINE**

  **Caution** The risk of drug dependence is high.

  **Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

  (i) chronic severe disabling pain associated with proven malignant neoplasia; or
  (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
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  (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

  **Note Shared Care Model:**
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Restricted benefit**

  Chronic severe disabling pain

  **Clinical criteria:**

  - The condition must be unresponsive to non-opioid analgesics.

### Buprenorphine 10 microgram/hour patch, 2

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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### Buprenorphine 40 microgram/hour patch, 2

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### Buprenorphine 30 microgram/hour patch, 2

<table>
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### Buprenorphine 20 microgram/hour patch, 2

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### Buprenorphine 25 microgram/hour patch, 2

<table>
<thead>
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<tr>
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<td>61.15</td>
<td>38.80</td>
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</table>
### NERVOUS SYSTEM

**buprenorphine 5 microgram/hour patch, 2**

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<tbody>
<tr>
<td>1</td>
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<td>28.62</td>
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**buprenorphine 15 microgram/hour patch, 2**

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td></td>
<td>47.33</td>
<td>38.80</td>
<td>Norspan [MF]</td>
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</tr>
</tbody>
</table>

### Opioids in combination with non-opioid analgesics

- **PARACETAMOL + CODEINE**

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

<table>
<thead>
<tr>
<th>3316M</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

*2.10 14.54 13.65 * Panadeine Forte [SW]

### PARACETAMOL + CODEINE

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

*2.10 14.54 13.65 * Panadeine Forte [SW]

### PARACETAMOL + CODEINE

**CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

*6.30 *21.43 16.34 * Panadeine Forte [SW]

### Other opioids

- **TAPENTADOL**

  **Caution** The risk of drug dependence is high.

  **Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
  (i) chronic severe disabling pain associated with proven malignant neoplasia; or
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  (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

  **Restricted benefit** Chronic severe disabling pain

  **Clinical criteria:** The condition must be unresponsive to non-opioid analgesics.
### NERVOUS SYSTEM

#### Tapentadol

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
<td>10.95</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>50 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
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<td>26.73</td>
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</tr>
<tr>
<td>250 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
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<tr>
<td>200 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
<td>47.62</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>100 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
<td>33.39</td>
<td>34.60</td>
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</tr>
</tbody>
</table>

#### Tramadol

**Tapentadol**

**Tapentadol hydrochloride 100 mg/mL oral liquid, 10 mL**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Manufacturer</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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</thead>
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<tr>
<td>100 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
<td>40.95</td>
<td>38.80</td>
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</table>

**Tapentadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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**Tramadol**

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<td>Palexia SR [CS]</td>
<td>33.39</td>
<td>34.60</td>
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</tbody>
</table>

**TRAMADOL**

- **Restricted benefit**
- Pain

#### Clinical criteria:
- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**Tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

<table>
<thead>
<tr>
<th>Product Description</th>
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<th>MRVSN $</th>
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**Tramadol hydrochloride 100 mg/mL injection, 5 x 2 mL ampoules**

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**Tramadol hydrochloride 100 mg modified release tablet, 28**

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<tr>
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<td>Palexia SR [CS]</td>
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<td>34.60</td>
<td></td>
</tr>
</tbody>
</table>

**TRAMADOL**

- **Restricted benefit**
- Acute pain

#### Clinical criteria:
- The treatment must be for the short-term.

**Tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

<table>
<thead>
<tr>
<th>Product Description</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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**Tramadol hydrochloride 100 mg/mL injection, 5 x 2 mL ampoules**

<table>
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<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
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</table>

**Tramadol hydrochloride 100 mg modified release tablet, 28**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>100 mg modified release tablet, 28</td>
<td>Palexia SR [CS]</td>
<td>33.39</td>
<td>34.60</td>
<td></td>
</tr>
</tbody>
</table>

**TRAMADOL**

- **Restricted benefit**
- Pain

#### Clinical criteria:
- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

**Tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

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<thead>
<tr>
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**Tramadol hydrochloride 100 mg/mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
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**TRAMADOL**

- **Restricted benefit**
- Acute pain

#### Clinical criteria:
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<td></td>
</tr>
</tbody>
</table>
TRAMADOL

Restricted benefit
Acute pain
Clinical criteria:
• The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

Restricted benefit
Chronic pain
Treatment Phase: Dose titration
Clinical criteria:
• The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
NERVOUS SYSTEM

General Pharmaceutical Benefits

Restricted benefit
Acute pain
Clinical criteria:
• The treatment must be for the short-term.

Tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

<table>
<thead>
<tr>
<th>8582Q</th>
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<tr>
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<td>13.94</td>
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<td>Tramadol 100 [CS]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tramadol Sandoz [SZ]</td>
</tr>
</tbody>
</table>

TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Chronic pain
Treatment Phase: Dose titration
Clinical criteria:
• The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

Tramadol hydrochloride 50 mg capsule, 20

<table>
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<th>8611F</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>2</td>
<td>13.09</td>
<td>14.30</td>
<td>*</td>
<td>APO-Tramadol [TX]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>Terry White Chemists</td>
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<tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Tramadol [TW]</td>
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<td></td>
<td>Tramadol AN [EA]</td>
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<tr>
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<td></td>
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<td></td>
<td>Tramadol SCP [CR]</td>
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<td></td>
<td>Zydol [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tramadol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tramado [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.42</td>
<td>15.51</td>
<td>14.30</td>
<td>* Tramal [CS]</td>
</tr>
</tbody>
</table>

OTHER ANALGESICS AND ANTIPYRETICS

Salicylic acid and derivatives

ASPIRIN

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

Aspirin 300 mg effervescent tablet, 96

<table>
<thead>
<tr>
<th>1010E</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>12.61</td>
<td>13.82</td>
<td>Solprin [RC]</td>
<td></td>
</tr>
</tbody>
</table>

ASPIRIN

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

Aspirin 300 mg effervescent tablet, 96

<table>
<thead>
<tr>
<th>5018D</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>12.61</td>
<td>13.82</td>
<td>Solprin [RC]</td>
<td></td>
</tr>
</tbody>
</table>

Anilides

PARACETAMOL

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

Paracetamol 120 mg/5 mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>1747Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>13.66</td>
<td>14.87</td>
<td>Panamax [SW]</td>
<td></td>
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</table>

Paracetamol 500 mg tablet, 100

<table>
<thead>
<tr>
<th>1746X</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>12.74</td>
<td>13.95</td>
<td>APO-Paracetamol [TX]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Generic Health Pty Ltd [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paracetamol (Sandoz) [SZ]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Parapane [AF]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Febrido [EA]</td>
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<td></td>
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<td>Paralgin [OW]</td>
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Paracetamol 240 mg/5 mL oral liquid, 200 mL

<table>
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<tr>
<th>1770E</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>14.79</td>
<td>16.00</td>
<td>Panamax 240 Elixir [SW]</td>
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</table>
### PARACETAMOL

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

#### paracetamol 120 mg/5 mL oral liquid, 100 mL

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<td>14.87</td>
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<td>13.95</td>
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<tr>
<td>* Febridol [EA]</td>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>16.00</td>
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### PARACETAMOL

**Restricted benefit**

Chronic arthropathies

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

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<tr>
<td>* APO-Paracetamol [TX]</td>
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<td>17.24</td>
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<td></td>
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#### paracetamol 665 mg tablet: modified release, 192

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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Osteomol 665 Paracetamol [CR]</td>
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<td>5</td>
<td>18.55</td>
<td>19.76</td>
<td></td>
</tr>
</tbody>
</table>

### PARACETAMOL

**Note**

Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

#### paracetamol 665 mg modified release tablet, 96

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<thead>
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<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>APOHEALTH Osteo Relief Paracetamol 665 mg [TX]</td>
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<td>5</td>
<td>*18.55</td>
<td>19.76</td>
<td></td>
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<tr>
<td>Osteomol 665 Paracetamol [CR]</td>
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<td></td>
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</table>

### Other analgesics and antipyretics
PREGABALIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4172
Neuropathic pain
Clinical criteria:
• The condition must be refractory to treatment with other drugs.

pregabalin 150 mg capsule, 56

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
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<th>DPMQ</th>
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</table>

* APO-Pregabalin [TX]
* LYRALIN [RW]
* Lyzalon [AF]
* Pregabalin AMNEAL [EZ]
* PREGABALIN-DRLA [RZ]
* Pregabalin Sandoz [SZ]
* Blooms The Chemist Pregabalin [IB]
* Lyrica [PF]
* Neurocord [CR]
* Pregabalin APOTEX [GX]
* Pregabalin GH [GQ]
* Pregabalin-Teva [TB]

pregabalin 75 mg capsule, 56

<table>
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<th>No. of Rpts</th>
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* APO-Pregabalin [TX]
* LYRALIN [RW]
* Lyzalon [AF]
* Pregabalin AMNEAL [EZ]
* PREGABALIN-DRLA [RZ]
* Pregabalin Sandoz [SZ]
* Blooms The Chemist Pregabalin [IB]
* Lyrica [PF]
* Neurocord [CR]
* Pregabalin APOTEX [GX]
* Pregabalin GH [GQ]
* Pregabalin-Teva [TB]

pregabalin 25 mg capsule, 56

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* APO-Pregabalin [TX]
* LYRALIN [RW]
* Lyzalon [AF]
* Pregabalin AMNEAL [EZ]
* PREGABALIN-DRLA [RZ]
* Pregabalin Sandoz [SZ]
* Blooms The Chemist Pregabalin [IB]
* Lyrica [PF]
* Neurocord [CR]
* Pregabalin APOTEX [GX]
* Pregabalin GH [GQ]
* Pregabalin-Teva [TB]

pregabalin 300 mg capsule, 56

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* APO-Pregabalin [TX]
* LYRALIN [RW]
* Lyzalon [AF]
* Pregabalin AMNEAL [EZ]
* PREGABALIN-DRLA [RZ]
* Pregabalin Sandoz [SZ]
* Blooms The Chemist Pregabalin [IB]
* Lyrica [PF]
* Neurocord [CR]
* Pregabalin APOTEX [GX]
* Pregabalin GH [GQ]
* Pregabalin-Teva [TB]

ANTIMIGRAINE PREPARATIONS

Selective serotonin (5HT1) agonists

ELETRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Migraine attack
Clinical criteria:
• The condition must have usually failed to respond to analgesics in the past.
**Nervous System**

**Eletriptan 40 mg tablet, 4**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5290K</td>
<td></td>
<td>1 26.24</td>
<td></td>
<td>27.45</td>
<td>Relpa [PF]</td>
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</table>

**Eletriptan 80 mg tablet, 4**

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5291L</td>
<td></td>
<td>1 26.24</td>
<td></td>
<td>27.45</td>
<td>Relpa [PF]</td>
</tr>
</tbody>
</table>

**Naratryptan**

Caution: Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past.

**Naratryptan 2.5 mg tablet, 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>8298R</td>
<td></td>
<td>2 2.28</td>
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<td>28.40</td>
<td>Naramig [AS]</td>
</tr>
</tbody>
</table>

**Naratryptan**

Caution: Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**Authority required**
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

**Authority required**
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Authority required**
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

**Authority required**
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

**Naratryptan 2.5 mg tablet, 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>9734H</td>
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<td>2 29.47</td>
<td>30.68</td>
<td></td>
<td>Naramig [AS]</td>
</tr>
</tbody>
</table>
- **RIZATRIPTAN**

  **Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

  **Note** No increase in the maximum quantity or number of units may be authorised.

  **Note** No increase in the maximum number of repeats may be authorised.

  **Note** Continuing Therapy Only:

  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Note** Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

  **Restricted benefit**

  Migraine attack

  **Clinical criteria:**

  - The condition must have usually failed to respond to analgesics in the past.

  **rizatriptan 10 mg orally disintegrating tablet, 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<tbody>
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<td></td>
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<td>22.12</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>MAXATAN [RW]</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Rizatriptan ODT GH [GQ]</em></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Chem mart Rizatriptan [CH]</em></td>
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<tr>
<td></td>
<td><em>Rizatriptan Wafers-10mg [AF]</em></td>
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  **rizatriptan 10 mg wafer, 2**

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<td></td>
<td><em>Rizatriptan Wafers-10mg [AF]</em></td>
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</tbody>
</table>

- **SUMATRIPTAN**

  **Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

  **Note** No increase in the maximum quantity or number of units may be authorised.

  **Note** No increase in the maximum number of repeats may be authorised.

  **Note** Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

  **Note** Continuing Therapy Only:

  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Restricted benefit**

  Migraine attack

  **Clinical criteria:**

  - The condition must have usually failed to respond to analgesics in the past.

  **sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation**

<table>
<thead>
<tr>
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<tr>
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  **SUMATRIPTAN Tablet 50 mg (as succinate), 2**

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<th>MRVSN $</th>
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<td></td>
<td><em>Iptam [AL]</em></td>
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<tr>
<td></td>
<td><em>Sumatriptan Sandoz [SZ]</em></td>
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<tr>
<td></td>
<td><em>Chem mart Sumatriptan [CH]</em></td>
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<td></td>
</tr>
<tr>
<td></td>
<td><em>Sumatran [OW]</em></td>
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<td></td>
<td><em>Terry White Chemists Sumatriptan [TW]</em></td>
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<td><em>Imigran [LN]</em></td>
<td>20.45</td>
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  **SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4**

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<td>Imigran FDT [AS]</td>
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  **SUMATRIPTAN Tablet 50 mg tablet, 4**

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<tr>
<td></td>
<td><em>Iptam [AL]</em></td>
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<tr>
<td></td>
<td><em>Sumatran [OW]</em></td>
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<td><em>Sumatriptan generichealth [GQ]</em></td>
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<td><em>Sumatriptan RBX [RA]</em></td>
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</table>
ZOMITRIPTAN
Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Migraine attack
Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past.

Zolmitriptan 2.5 mg tablet, 2

Other antimigraine preparations

CYPROHEPTADINE
Note Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Prevention of migraine

Cyproheptadine hydrochloride 4 mg tablet, 100

PIZOTIFEN
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Pizotifen 500 microgram tablet, 100

ANTIEPILEPTICS

ANTIEPILEPTICS
Barbiturates and derivatives

PHENOBARBITONE
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Epilepsy

Phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules
NERVOUS SYSTEM

phenobarbitone 30 mg tablet, 200
1850J

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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PRIMIDONE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

primidone 250 mg tablet, 200
1939C

<table>
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<th>MRVSN $</th>
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<tr>
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<td>77.64</td>
<td>38.80</td>
<td>Mysoline [LM]</td>
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</table>

Hydantoin derivatives

PHENYTOIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

phenytoin sodium 30 mg capsule, 200
1873N

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<tr>
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<td>31.08</td>
<td>32.29</td>
<td>Dilantin Sodium [PF]</td>
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</table>

phenytoin 30 mg/5 mL oral liquid, 500 mL
2692Q

<table>
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<th>Max Qty Packs</th>
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<tr>
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<td>3</td>
<td>..</td>
<td>30.81</td>
<td>32.02</td>
<td>Dilantin [PF]</td>
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phenytoin 50 mg chewable tablet, 200
1249R

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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
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<td>..</td>
<td>48.49</td>
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<td>Dilantin Infatabs [PF]</td>
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</table>

phenytoin sodium 100 mg capsule, 200
1874P

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>1</td>
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<td>..</td>
<td>34.85</td>
<td>36.06</td>
<td>Dilantin Sodium [PF]</td>
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</tbody>
</table>

Succinimide derivatives

ETHOSUXIMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

ethosuximide 250 mg/5 mL oral liquid, 200 mL
1414K

<table>
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<tr>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>29.81</td>
<td>31.02</td>
<td>Zarontin [IX]</td>
</tr>
</tbody>
</table>

ethosuximide 250 mg capsule, 200
1413J

<table>
<thead>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>76.27</td>
<td>38.80</td>
<td>Zarontin [IX]</td>
</tr>
</tbody>
</table>

Benzodiazepine derivatives

CLONAZEPAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Epilepsy

clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack
1807D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>21.66</td>
<td>22.87</td>
<td>Rivotril [RO]</td>
</tr>
</tbody>
</table>
**CLONAZEPAM**

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

**Epilepsy**

**Clinical criteria:**
- The condition must be neurologically proven.

<table>
<thead>
<tr>
<th>clonazepam 2 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1806C</td>
</tr>
<tr>
<td>2</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>clonazepam 2.5 mg/mL oral liquid, 10 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<td>1808E</td>
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<table>
<thead>
<tr>
<th>clonazepam 500 microgram tablet, 100</th>
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<td>Max Qty Packs</td>
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<tr>
<td>1805B</td>
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</table>

**NITRAZEPAM**

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

**Myoclonic epilepsy**

**Authority required**

**Malignant neoplasia (late stage)**

**Authority required**

**Insomnia**

**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

<table>
<thead>
<tr>
<th>nitrazepam 5 mg tablet, 25</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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<td>3</td>
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</table>

**Carboxamide derivatives**

**CARBAMAZEPINE**

<table>
<thead>
<tr>
<th>carbamazepine 100 mg/5 mL oral liquid, 300 mL</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>5041H</td>
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<table>
<thead>
<tr>
<th>carbamazepine 200 mg modified release tablet, 200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>5038E</td>
</tr>
</tbody>
</table>
### CARBAMAZEPINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Carbamazepine Sandoz [SZ]</td>
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<td>*2.96</td>
<td>*33.69</td>
<td>31.94</td>
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<tr>
<td>Tegretol 200 [NV]</td>
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<td>4.90</td>
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<td>31.94</td>
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</table>

### OXCARBAZEPINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

Seizures

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, AND
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
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<td>38.80</td>
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<tr>
<td>Trileptal [NV]</td>
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<tr>
<td>Trileptal [NV]</td>
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<td>..</td>
<td>*124.83</td>
<td>38.80</td>
<td>38.80</td>
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</tbody>
</table>
NERVOUS SYSTEM

oxcarbazepine 300 mg tablet, 100
858SW
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 104.93 38.80 Trileptal [NV]

Fatty acid derivatives

TIAGABINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4928
Partial epileptic seizures
Clinical criteria:
• The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

tiagabine 15 mg tablet, 50
8223T
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 5 .. *175.57 38.80 Gabitril [OA]

tiagabine 5 mg tablet, 50
8221Q
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 5 .. *68.27 38.80 Gabitril [OA]

tiagabine 10 mg tablet, 50
8222R
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 5 .. *125.45 38.80 Gabitril [OA]

VALPROATE

Caution There are reports of fatal hepatotoxicity, particularly in children. There is increasing evidence of dose-related teratogenesis from this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

valproate sodium 100 mg tablet, 100
2294R
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 2 .. *33.33 34.54 Epilim [SW]

valproate sodium 200 mg/5 mL oral liquid, 300 mL
2293Q
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 2 .. *39.05 38.80 Epilim Liquid [SW]

valproate sodium 200 mg/5 mL oral liquid, 300 mL
2295T
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 2 .. *39.05 38.80 Epilim Syrup [SW]

valproate sodium 200 mg enteric tablet, 100
2289L
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 2 .. *22.83 24.04 * Sodium Valproate Sandoz [SZ] * Valpro 200 [AF] * Valproate Winthrop EC 200 [WA]

2.00 *24.83 24.04 Epilim EC [SW]

valproate sodium 500 mg enteric tablet, 100
2290M
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 2 .. *34.33 35.54 * Sodium Valproate Sandoz [SZ] * Valpro 500 [AF] * Valproate Winthrop EC 500 [WA]

2.00 *36.33 35.54 Epilim EC [SW]

VIGABATRIN

Caution Visual field defects have been reported with this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4929**

Epileptic seizures

**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Vigabatrin 500 mg tablet, 100**

<table>
<thead>
<tr>
<th>MaxQty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>2667J</td>
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<td>108.13</td>
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<td>Sabril [SW]</td>
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</table>

**Vigabatrin 500 mg powder for oral liquid, 60 sachets**

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<th>Premium $</th>
<th>DPMQ $</th>
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<td>73.90</td>
<td>38.80</td>
<td>Sabril [SW]</td>
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</tbody>
</table>

**Other antiepileptics**

**GABAPENTIN**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4928**

Partial epileptic seizures

**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Gabapentin 400 mg capsule, 100**

<table>
<thead>
<tr>
<th>MaxQty Packs</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>Gabapentin GH [GQ]</td>
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<td>Gabapentin Aspen 400 [RW]</td>
<td>GAPENTIN [RF]</td>
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<td></td>
<td>Gabapentin Sandoz [SZ]</td>
<td>Neurontin [PF]</td>
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<td></td>
<td></td>
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<td></td>
<td>Nupentin 400 [AF]</td>
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</table>

**Gabapentin 600 mg tablet, 100**

<table>
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<th>Brand Name and Manufacturer</th>
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<td>Gabapentin AN [EA]</td>
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<td></td>
<td>Gabapentin Aspen 600 [RW]</td>
<td>Gabapentin GH [GQ]</td>
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<td></td>
<td>GAPENTIN [RF]</td>
<td>Gabapentin [RF]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Neurontin [PF]</td>
<td>Nupentin Tabs [AF]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Pharmacor Gabapentin 600 [CR]</td>
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</table>

**Gabapentin 300 mg capsule, 100**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>Gabapentin AN [EA]</td>
<td>Gabapentin AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>Gabapentin Aspen 300 [RW]</td>
<td>Gabapentin GH [GQ]</td>
</tr>
<tr>
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<td></td>
<td>Gabapentin Sandoz [SZ]</td>
<td>Gabapentin [RF]</td>
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<td></td>
<td></td>
<td>GenRx Gabapentin [GX]</td>
<td>Neurontin [PF]</td>
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<td>Nupentin 300 [AF]</td>
<td>Pharmacor Gabapentin 300 [CR]</td>
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**Gabapentin 800 mg tablet, 100**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<td>Gabapentin AN [EA]</td>
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<td></td>
<td>Gabapentin Aspen 800 [RW]</td>
<td>Gabapentin GH [GQ]</td>
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<td>GAPENTIN [RF]</td>
<td>Gabapentin [RF]</td>
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<td>Neurontin [PF]</td>
<td>Neurontin Tabs [AF]</td>
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<td>Pharmacor Gabapentin 800 [CR]</td>
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**Gabapentin 100 mg capsule, 100**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
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<td>15.13</td>
<td>16.34</td>
<td>APO-Gabapentin [TX]</td>
<td>Gabapentin AN [EA]</td>
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<td>Gabapentin Aspen 100 [RW]</td>
<td>Gabapentin GH [GQ]</td>
</tr>
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<td></td>
<td>GAPENTIN [RF]</td>
<td>Gabapentin [RF]</td>
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<td></td>
<td>Neurontin [PF]</td>
<td>Neurontin Tabs [AF]</td>
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<td></td>
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<td>Pharmacor Gabapentin 100 [CR]</td>
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</tbody>
</table>

**LACOSAMIDE**

**Note Continuing Therapy Only:**
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patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4271
Intractable partial epileptic seizures
Treatment Phase: Initial

Treatment criteria:
• Must be treated by a neurologist.

Clinical criteria:
• The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND
• The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, AND
• The treatment must be for dose titration purposes.

Population criteria:
• Patient must be aged 16 years or older.

lacosamide 150 mg tablet, 14

9336J
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. 70.04 38.80 Vimpat [UC]

lacosamide 100 mg tablet, 14

9334G
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. 50.40 38.80 Vimpat [UC]

lacosamide 50 mg tablet, 14

9333F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. 30.74 31.95 Vimpat [UC]

LACOSAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4249
Intractable partial epileptic seizures
Treatment Phase: Continuing

Clinical criteria:
• Patient must have previously been treated with PBS-subsidised lacosamide.

Population criteria:
• Patient must be aged 16 years or older.

lacosamide 50 mg tablet, 14

10293R
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
4 5 .. *89.71 38.80 Vimpat [UC]

LACOSAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4264
Intractable partial epileptic seizures
Treatment Phase: Initial

Treatment criteria:
• Must be treated by a neurologist.

Clinical criteria:
• The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND
• The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Population criteria:
• Patient must be aged 16 years or older.

Authority required (STREAMLINED)

4249
Intractable partial epileptic seizures
Treatment Phase: Continuing

Clinical criteria:
- Patient must have previously been treated with PBS-subsidised lacosamide.

Population criteria:
- Patient must be aged 16 years or older.

Lacosamide 100 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>Vipat [UC]</td>
</tr>
</tbody>
</table>

LACOSAMIDE

Note No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4240
Intractable partial epileptic seizures
Treatment Phase: Initial

Treatment criteria:
- Must be treated by a neurologist.

Clinical criteria:
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent. AND
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Population criteria:
- Patient must be aged 16 years or older.

Authority required (STREAMLINED)

4257
Intractable partial epileptic seizures
Treatment Phase: Continuing

Clinical criteria:
- Patient must have previously been treated with PBS-subsidised lacosamide.

Population criteria:
- Patient must be aged 16 years or older.

Lacosamide 200 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td></td>
<td></td>
<td></td>
<td>Vipat [UC]</td>
</tr>
</tbody>
</table>

LAMOTRIGINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5138
Epileptic seizures

Clinical criteria:
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

Lamotrigine 100 mg tablet, 56

<table>
<thead>
<tr>
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### LEVETIRACETAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4928**

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### Levetiracetam 250 mg tablet, 60

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#### Levetiracetam 500 mg tablet, 60

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### LEVETIRACETAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5215**
Partial epileptic seizures

**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of levetiracetam.

**levetiracetam 100 mg/mL oral liquid, 300 mL**

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</table>

### PERAMPRINT

**Authority required (STREAMLINED)**

**4656**
Intractable partial epileptic seizures

**Treatment Phase: Initial**

**Clinical criteria:**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Treatment criteria:**
- Must be treated by a neurologist.

**peramprint 2 mg tablet, 7**

<table>
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<tr>
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### PERAMPRINT

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4658**
Intractable partial epileptic seizures

**Treatment Phase: Continuing**

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug.

**peramprint 10 mg tablet, 28**

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**peramprint 6 mg tablet, 28**

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**peramprint 12 mg tablet, 28**

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**peramprint 4 mg tablet, 28**

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**peramprint 8 mg tablet, 28**

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NERVOUS SYSTEM

- **SULTHIAME**

  **Note** Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **sulthiame 50 mg tablet, 200**

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  **sulthiame 200 mg tablet, 200**

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- **TOPIRAMATE**

  **Note** Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Authority required (STREAMLINED)**

  5516
  Seizures
  Clinical criteria:
  - Patient must have partial epileptic seizures; OR
  - Patient must have primary generalised tonic-clonic seizures; OR
  - Patient must have seizures of the Lennox-Gastaut syndrome, AND
  - The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

  **topiramate 100 mg tablet, 60**

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<td>Topamax [JC]</td>
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  **topiramate 200 mg tablet, 60**

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- **TOPIRAMATE**

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  **Authority required (STREAMLINED)**

  5173
  Seizures
  Clinical criteria:
  - Patient must have partial epileptic seizures; OR
  - Patient must have primary generalised tonic-clonic seizures; OR
  - Patient must have seizures of the Lennox-Gastaut syndrome, AND
  - The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, AND
  - Patient must be unable to take a solid dose form of topiramate.

  **topiramate 25 mg capsule, 60**

<table>
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  **topiramate 15 mg capsule, 60**

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### TOPIRAMATE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

#### 5516
**Seizures**

**Clinical criteria:**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)**

#### 5325
**Migraine**

**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient’s medical records when treatment is initiated.

### ZONISAMIDE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

#### 4928
**Partial epileptic seizures**

**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

### ZONISAMIDE 50 mg capsule, 56

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### ZONISAMIDE 25 mg capsule, 56

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### ZONISAMIDE 50 mg tablet, 56

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<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>22.21</td>
<td>23.42</td>
<td>APO-Zonisamide [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>22.21</td>
<td>23.42</td>
<td>Epiramax 50 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>22.21</td>
<td>23.42</td>
<td>Tamate [AF]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>22.21</td>
<td>23.42</td>
<td>Topiramate AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>22.21</td>
<td>23.42</td>
<td>Topiramate GH [GQ]</td>
</tr>
<tr>
<td></td>
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<td>22.21</td>
<td>23.42</td>
<td>Topiramate Sandoz [SZ]</td>
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</table>

### ZONISAMIDE 25 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>30.04</td>
<td>31.25</td>
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<tr>
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<td>30.04</td>
<td>31.25</td>
<td>Zonegran [SA]</td>
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### ZONISAMIDE 50 mg capsule, 56

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>22.45</td>
<td>23.66</td>
<td>APO-Zonisamide [TX]</td>
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<td></td>
<td></td>
<td>22.45</td>
<td>23.66</td>
<td>Zonegran [SA]</td>
</tr>
</tbody>
</table>

### ZONISAMIDE 25 mg capsule, 56
## NERVOUS SYSTEM

### ANTIPARKINSON DRUGS

#### ANTI-PARKINSON DRUGS

#### BENZHEXOL

**Benzhexol hydrochloride 5 mg tablet, 200**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1110K</td>
<td>1</td>
<td>24.50</td>
<td>25.71</td>
<td>Artane [RW]</td>
<td></td>
</tr>
</tbody>
</table>

**Benzhexol hydrochloride 2 mg tablet, 200**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1109J</td>
<td>1</td>
<td>18.85</td>
<td>20.06</td>
<td>Artane [RW]</td>
<td></td>
</tr>
</tbody>
</table>

#### BIPERIDEN

Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Biperiden hydrochloride 2 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2544X</td>
<td>2</td>
<td>23.05</td>
<td>24.26</td>
<td>Akineton [GH]</td>
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</tr>
</tbody>
</table>

#### BENZATROPINE

**Benzatropine mesilate 2 mg tablet, 60**

<table>
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<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2362H</td>
<td>1</td>
<td>18.28</td>
<td>19.49</td>
<td>Benzatrop [PL]</td>
<td></td>
</tr>
</tbody>
</table>

**Benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3038X</td>
<td>1</td>
<td>95.01</td>
<td>38.80</td>
<td>Cogentin [FK]</td>
<td></td>
</tr>
</tbody>
</table>

**Benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5031T</td>
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<td>95.01</td>
<td>38.80</td>
<td>Cogentin [FK]</td>
<td></td>
</tr>
</tbody>
</table>

**Benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10013B</td>
<td>1</td>
<td>263.28</td>
<td>38.80</td>
<td>Benzatropine Omega [FK]</td>
<td></td>
</tr>
</tbody>
</table>

**Benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10027R</td>
<td>1</td>
<td>263.28</td>
<td>38.80</td>
<td>Benzatropine Omega [FK]</td>
<td></td>
</tr>
</tbody>
</table>

#### DOPAMINERGIC AGENTS

#### LEVODOPA + BENSERAZIDE

Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Levodopa 100 mg + benzerazide 25 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2229H</td>
<td>1</td>
<td>37.94</td>
<td>38.80</td>
<td>Madopar 125 [RO]</td>
<td></td>
</tr>
</tbody>
</table>
**NERVOUS SYSTEM**

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2231K</td>
<td>1</td>
<td>5</td>
<td>40.61</td>
<td>38.80</td>
<td>Madopar HBS [RO]</td>
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</tbody>
</table>

**LEVDOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8219N</td>
<td>1</td>
<td>5</td>
<td>37.94</td>
<td>38.80</td>
<td>Madopar Rapid 125 [RO]</td>
</tr>
</tbody>
</table>

**levodopa 200 mg + benserazide 50 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2226E</td>
<td>1</td>
<td>5</td>
<td>48.23</td>
<td>38.80</td>
<td>Madopar 125 [RO]</td>
</tr>
</tbody>
</table>

**LEVDOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8218M</td>
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<td>5</td>
<td>24.79</td>
<td>26.00</td>
<td>Madopar Rapid 62.5 [RO]</td>
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</tbody>
</table>

**levodopa 100 mg + benserazide 25 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2225D</td>
<td>1</td>
<td>5</td>
<td>37.94</td>
<td>38.80</td>
<td>Madopar 125 [RO]</td>
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</tbody>
</table>

**levodopa 200 mg + benserazide 50 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2226G</td>
<td>1</td>
<td>5</td>
<td>48.23</td>
<td>38.80</td>
<td>Madopar 125 [RO]</td>
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</table>

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2227F</td>
<td>1</td>
<td>5</td>
<td>24.79</td>
<td>26.00</td>
<td>Madopar 62.5 [RO]</td>
</tr>
</tbody>
</table>

**LEVDOPA + CARBIDOPA ANHYDROUS**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1245M</td>
<td>1</td>
<td>5</td>
<td>45.26</td>
<td>38.80</td>
<td>Sinemet [MK]</td>
</tr>
</tbody>
</table>

**levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1242J</td>
<td>1</td>
<td>5</td>
<td>38.80</td>
<td>38.80</td>
<td>* Kinson [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.85</td>
<td>43.65</td>
<td>* Sinemet 100/25 [MK]</td>
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</tbody>
</table>

**LEVDOPA + CARBIDOPA ANHYDROUS**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

**Clinical criteria:**
- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**levodopa 200 mg + carbidopa anhydrous 50 mg modified release tablet, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1255C</td>
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<td>5</td>
<td>66.95</td>
<td>38.80</td>
<td>Sinemet CR [MK]</td>
</tr>
</tbody>
</table>

**LEVDOPA + CARBIDOPA ANHYDROUS**

**Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.**

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STANDARD)**
5473
Advanced Parkinson disease
Treatment Phase: Maintenance therapy
Clinical criteria:
• Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND
• Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8</td>
<td>5</td>
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<td>11685.47</td>
<td>38.80</td>
<td>Duodopa [VE]</td>
</tr>
</tbody>
</table>

**LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE**

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease
Clinical criteria:
• Patient must be being treated with levodopa decarboxylase inhibitor combinations, AND
• Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**
Parkinson disease
Clinical criteria:
• Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9292C</td>
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<td>393.13</td>
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<td>Stalevo 200/50/200mg [NV]</td>
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<tr>
<td>8797B</td>
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<td>..</td>
<td>302.31</td>
<td>38.80</td>
<td>Stalevo 50/12.5/200mg [NV]</td>
</tr>
<tr>
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<td>316.01</td>
<td>38.80</td>
<td>Stalevo 75/18.75/200mg [NV]</td>
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<td>333.41</td>
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<td>Stalevo 100/25/200mg [NV]</td>
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<td>345.87</td>
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<td>Stalevo 125/31.25/200mg [NV]</td>
</tr>
<tr>
<td>8799D</td>
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<td>..</td>
<td>364.49</td>
<td>38.80</td>
<td>Stalevo 150/37.5/200mg [NV]</td>
</tr>
</tbody>
</table>

Adamantane derivatives

**AMANTADINE**

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease
Clinical criteria:
• The condition must not be drug induced.

amantadine hydrochloride 100 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3016R</td>
<td>5</td>
<td>..</td>
<td>42.81</td>
<td>38.80</td>
<td>Symmetrel 100 [NV]</td>
</tr>
</tbody>
</table>

Dopamine agonists
## BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

- Acromegaly
- Parkinson disease
- Pathological hyperprolactinaemia

**Clinical criteria:**
- Patient must be one in whom surgery is not indicated.
- Patient must have had surgery for this condition with incomplete resolution.
- Patient must have had radiotherapy for this condition with incomplete resolution.

<table>
<thead>
<tr>
<th>bromocriptine 2.5 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>1443Y</td>
</tr>
</tbody>
</table>

## CABERGOLINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit** Parkinson disease

<table>
<thead>
<tr>
<th>cabergoline 2 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>8394T</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>cabergoline 1 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>8393R</td>
</tr>
</tbody>
</table>

## PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note Continuing Therapy Only:** For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit** Parkinson disease

<table>
<thead>
<tr>
<th>pramipexole hydrochloride monohydrate 1 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>9153R</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>pramipexole hydrochloride monohydrate 125 microgram tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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</tr>
<tr>
<td>9151P</td>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>
### NERVOUS SYSTEM

#### PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Continuing Therapy Only: 
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

### pramipexole hydrochloride monohydrate 250 microgram tablet, 100

<table>
<thead>
<tr>
<th>9152Q</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>28.97</td>
<td>30.18</td>
<td>* APO-Pramipexole [TX]</td>
<td>* Pramipexole AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pramipexole GH [GQ]</td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Simipex 0.25 [RW]</td>
<td>* Simipex [AF]</td>
</tr>
</tbody>
</table>

### pramipexole hydrochloride monohydrate 2.25 mg modified release tablet, 30

<table>
<thead>
<tr>
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<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<td>* Pramipexole XR GP [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
</tr>
</tbody>
</table>

### pramipexole hydrochloride monohydrate 375 microgram modified release tablet, 30

<table>
<thead>
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<tbody>
<tr>
<td>NP</td>
<td>1</td>
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<td>..</td>
<td>18.85</td>
<td>20.06</td>
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<td>* Pramipexole XR GP [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
</tr>
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</table>

### pramipexole hydrochloride monohydrate 4.5 mg modified release tablet, 30

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
<td>1</td>
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<td>..</td>
<td>111.03</td>
<td>38.80</td>
<td>* APO-Pramipexole ER [TX]</td>
<td>* Pramipexole XR GP [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
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### pramipexole hydrochloride monohydrate 3 mg modified release tablet, 30

<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>77.72</td>
<td>38.80</td>
<td>* APO-Pramipexole ER [TX]</td>
<td>* Pramipexole XR GP [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
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</table>

### pramipexole hydrochloride monohydrate 3.75 mg modified release tablet, 30

<table>
<thead>
<tr>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>92.98</td>
<td>38.80</td>
<td>* APO-Pramipexole ER [TX]</td>
<td>* Pramipexole XR GP [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
</tr>
</tbody>
</table>

### pramipexole hydrochloride monohydrate 750 microgram modified release tablet, 30

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>26.36</td>
<td>27.57</td>
<td>* APO-Pramipexole ER [TX]</td>
<td>* Pramipexole XR GP [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
</tr>
</tbody>
</table>

### pramipexole hydrochloride monohydrate 1.5 mg modified release tablet, 30

<table>
<thead>
<tr>
<th>3420B</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>41.63</td>
<td>38.80</td>
<td>* APO-Pramipexole ER [TX]</td>
<td>* Pramipexole XR GP [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol ER [BY]</td>
<td>* SIMIPEX XR [RW]</td>
</tr>
</tbody>
</table>

#### PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug. Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Primary severe restless legs syndrome

**Clinical criteria:**
- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
• Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole. The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:
(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and
(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

### pramipexole hydrochloride monohydrate 125 microgram tablet, 30

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>13.82</td>
<td>15.03</td>
<td></td>
<td>Sifrol [BY]</td>
</tr>
</tbody>
</table>

### pramipexole hydrochloride monohydrate 250 microgram tablet, 100

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>28.97</td>
<td>30.18</td>
<td></td>
<td>Sifrol [BY]</td>
</tr>
</tbody>
</table>

### ROTIGOTINE

**Restricted benefit**
Parkinson disease

**Clinical criteria:**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

#### rotigotine 8 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>119.43</td>
<td>38.80</td>
<td></td>
<td>Neupro [UC]</td>
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</tbody>
</table>

#### rotigotine 4 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>96.94</td>
<td>38.80</td>
<td></td>
<td>Neupro [UC]</td>
</tr>
</tbody>
</table>

#### rotigotine 6 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>108.51</td>
<td>38.80</td>
<td></td>
<td>Neupro [UC]</td>
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</tbody>
</table>

### ROTIGOTINE

**Restricted benefit**
Parkinson disease

**Clinical criteria:**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

#### rotigotine 2 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>75.48</td>
<td>38.80</td>
<td></td>
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</tr>
</tbody>
</table>

**Monoamine oxidase B inhibitors**

### RASAGILINE

**Restricted benefit**
Parkinson disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### RASAGILINE Tablet 1 mg (as mesilate), 30

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Units</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>115.79</td>
<td>38.80</td>
<td></td>
<td>Azilect [TB]</td>
</tr>
</tbody>
</table>

### SELEGILINE

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Late stage Parkinson disease
NERVOUS SYSTEM

**Clinical criteria:**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**selegiline hydrochloride 5 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1973W</td>
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<td>..</td>
<td>53.13</td>
<td>38.80</td>
<td>Eldepryl [AS]</td>
</tr>
</tbody>
</table>

**Other dopaminergic agents**

**ENTACAPONE**

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Parkinson disease

**Clinical criteria:**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, AND
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**entacapone 200 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8367J</td>
<td>4</td>
<td>..</td>
<td>*257.89</td>
<td>38.80</td>
<td>Comtan [NV]</td>
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</tbody>
</table>

**PSYCHOLEPTICS**

**ANTIPSYCHOTICS**

Phenothiazines with aliphatic side-chain

**CHLORPROMAZINE**

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**chlorpromazine hydrochloride 100 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1199D</td>
<td>5</td>
<td>..</td>
<td>20.19</td>
<td>21.40</td>
<td>Largactil [SW]</td>
</tr>
</tbody>
</table>

**chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1195X</td>
<td>...</td>
<td>..</td>
<td>22.70</td>
<td>23.91</td>
<td>Largactil [SW]</td>
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</table>

**chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL**

<table>
<thead>
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<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>1201F</td>
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<td>16.35</td>
<td>17.56</td>
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**chlorpromazine hydrochloride 10 mg tablet, 100**

<table>
<thead>
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<th>MRVSN $</th>
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**chlorpromazine hydrochloride 25 mg tablet, 100**

<table>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<td>..</td>
<td>15.28</td>
<td>16.49</td>
<td>Largactil [SW]</td>
</tr>
</tbody>
</table>

Phenothiazines with piperazine structure

**TRIFLUOPERAZINE**

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**trifluoperazine 2 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2386N</td>
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<td>..</td>
<td>23.50</td>
<td>24.71</td>
<td>Stelazine [GH]</td>
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</table>
## NERVOUS SYSTEM

### Trifluoperazine

<table>
<thead>
<tr>
<th>Trifluoperazine 1 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>2185B</td>
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<table>
<thead>
<tr>
<th>Trifluoperazine 5 mg tablet, 100</th>
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</thead>
<tbody>
<tr>
<td>2186C</td>
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<td>1</td>
</tr>
</tbody>
</table>

### Phenothiazines with piperidine structure

- **PERICYAZINE**
  
  **Note Shared Care Model:**
  
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Pericyazine 10 mg tablet, 100</th>
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<tr>
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</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pericyazine 2.5 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>3052P</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

### Butyrophenone derivatives

- **HALOPERIDOL**
  
  **Note Shared Care Model:**
  
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Haloperidol 2 mg/mL oral liquid, 100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2763K</td>
</tr>
<tr>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Haloperidol 5 mg tablet, 50</th>
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</thead>
<tbody>
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<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Haloperidol 5 mg/mL injection, 10 x 1 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>2768Q</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Haloperidol 1.5 mg tablet, 100</th>
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</thead>
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<table>
<thead>
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<th>Haloperidol 500 microgram tablet, 100</th>
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<tbody>
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<td>2761H</td>
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<td>1</td>
</tr>
</tbody>
</table>

### Haloperidol Decanoate

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>2766N</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>2765M</td>
</tr>
<tr>
<td>1</td>
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### Indole derivatives
**NERVOUS SYSTEM**

### LURASIDONE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
4246
Schizophrenia

**Lurasidone hydrochloride 80 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10529E</td>
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<td>..</td>
<td>144.35</td>
<td>38.80</td>
<td>Latuda [SE]</td>
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</table>

**Lurasidone hydrochloride 40 mg tablet, 30**

<table>
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<tbody>
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</table>

### ZIPRASIDONE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
4246
Schizophrenia

**Authority required (STREAMLINED)**
5742
Acute mania or mixed episodes

**Clinical criteria:**
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**Ziprasidone 60 mg capsule, 60**

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<tbody>
<tr>
<td>9072L</td>
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<td>144.63</td>
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**Ziprasidone 20 mg capsule, 60**

<table>
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<tbody>
<tr>
<td>9070J</td>
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<td>55.69</td>
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**Ziprasidone 80 mg capsule, 60**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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**Ziprasidone 40 mg capsule, 60**

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>9071K</td>
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<td>100.44</td>
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<td>* APO-Ziprasidone [TX] * Zeldox [PF]</td>
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**Thioxanthene derivatives**

### FLUPENTHIXOL DECANOATE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>2255Q</td>
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<td>23.34</td>
<td>24.55</td>
<td>Fluanxol Depot [LU]</td>
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**Flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules**

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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2257T</td>
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<td>48.44</td>
<td>38.80</td>
<td>Fluanxol Concentrated Depot [LU]</td>
<td></td>
</tr>
</tbody>
</table>
### ZUCLOPENTHIXOL DECANOATE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules</th>
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</thead>
<tbody>
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<td>8097E</td>
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<tr>
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<tr>
<td>8097E</td>
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</table>

**Diazepines, oxazepines, thiazepines and oxepines**

### ASENAPINE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4246**
Schizophrenia

**Authority required (STREAMLINED)**

**5773**
Acute mania or mixed episodes

**Clinical criteria:**
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)**

**5719**
Bipolar I disorder

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

<table>
<thead>
<tr>
<th>asenapine 10 mg sublingual wafer, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>5141N</td>
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<tr>
<td>------</td>
</tr>
<tr>
<td>5141N</td>
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</table>

<table>
<thead>
<tr>
<th>asenapine 5 mg sublingual wafer, 60</th>
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<tbody>
<tr>
<td>5140M</td>
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<tr>
<td>------</td>
</tr>
<tr>
<td>5140M</td>
</tr>
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</table>

### OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** Special Pricing Arrangements apply.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4304**
Schizophrenia

<table>
<thead>
<tr>
<th>olanzapine 300 mg modified release injection [1 vial] (＆) inert substance diluent [3 mL vial], 1 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>9295F</td>
</tr>
<tr>
<td>------</td>
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<tr>
<td>9295F</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>olanzapine 210 mg modified release injection [1 vial] (＆) inert substance diluent [3 mL vial], 1 pack</th>
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<tbody>
<tr>
<td>9294E</td>
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<td>------</td>
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<tr>
<td>9294E</td>
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</table>

<table>
<thead>
<tr>
<th>olanzapine 405 mg modified release injection [1 vial] (＆) inert substance diluent [3 mL vial], 1 pack</th>
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<tbody>
<tr>
<td>9303P</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>9303P</td>
</tr>
</tbody>
</table>
practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

### Authority required (STREAMLINED) 5856
**Schizophrenia**

### Authority required (STREAMLINED) 5869
**Bipolar I disorder**

**Clinical criteria:**
- The treatment must be maintenance therapy.

---

**olanzapine 7.5 mg tablet, 28**

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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* Olanzapine generichealth 7.5 [GQ]

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**olanzapine 7.5 mg tablet, 28**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<tr>
<td>8186W</td>
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<td>19.40</td>
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* APO-Olanzapine [TX]*
* Olanzacor 7.5 [CR]*
* Olanzapine-DRLA [RZ]*
* Olanzapine Sandoz [SZ]*
* Terry White Chemists Olanzapine [TW]*
* Zyprexa [LY]*

* Chem mart Olanzapine [CH]*
* Olanzapine AN [EA]*
* Olanzapine RBX [RA]*
* Ozin 7.5 [DO]*
* Zypine [AF]*

---

**olanzapine 10 mg tablet, 28**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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* Olanzapine generichealth 10 [GQ]

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**olanzapine 10 mg tablet, 28**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<tbody>
<tr>
<td>8187X</td>
<td>5</td>
<td>22.16</td>
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</table>

* APO-Olanzapine [TX]*
* Olanzacor 10 [CR]*
* Olanzapine-DRLA [RZ]*
* Olanzapine Sandoz [SZ]*
* Terry White Chemists Olanzapine [TW]*
* Zyprexa [LY]*

* Chem mart Olanzapine [CH]*
* Olanzapine AN [EA]*
* Olanzapine RBX [RA]*
* Ozin 10 [DO]*
* Zypine [AF]*

---

**olanzapine 5 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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* Olanzapine generichealth 5 [GQ]

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**olanzapine 5 mg tablet, 28**

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* APO-Olanzapine [TX]*
* Olanzacor 5 [CR]*
* Olanzapine-DRLA [RZ]*
* Olanzapine Sandoz [SZ]*
* Terry White Chemists Olanzapine [TW]*

* Chem mart Olanzapine [CH]*
* Olanzapine AN [EA]*
* Olanzapine RBX [RA]*
* Ozin 5 [DO]*
* Zypine [AF]*
### NERVOUS SYSTEM

#### OLANZAPINE

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### QUETIAPINE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
4246
Schizophrenia
NERVOUS SYSTEM

Authority required (STREAMLINED)

5611
Acute mania
Clinical criteria:
- The condition must be associated with bipolar I disorder, AND
- The treatment must be as monotherapy, AND
- The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)

5639
Bipolar I disorder
Clinical criteria:
- The treatment must be maintenance therapy.

quetiapine 100 mg tablet, 90

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>APO-Quetiapine [TX]</td>
<td>Chem mart Quetiapine [CH]</td>
</tr>
<tr>
<td>Delucon 100 [DO]</td>
<td>Kaptan [ER]</td>
</tr>
<tr>
<td>Pharmacor Quetiapine 100 [CR]</td>
<td>Quetia 100 [RW]</td>
</tr>
<tr>
<td>Quetiapine Actavis 100 [ED]</td>
<td>Quetiapine AN [EA]</td>
</tr>
<tr>
<td>Quetiapine-DRLA [RZ]</td>
<td>Quetiapine GH 100 [GQ]</td>
</tr>
<tr>
<td>Quetiapine RBX [RA]</td>
<td>Quetiapine Sandoz [SZ]</td>
</tr>
<tr>
<td>Seroquel [AP]</td>
<td>Syquet [AF]</td>
</tr>
<tr>
<td>Terry White Chemists Quetiapine [TW]</td>
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quetiapine 300 mg tablet, 60

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>APO-Quetiapine [TX]</td>
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<td>Quetia 300 [RW]</td>
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<td>Quetiapine AN [EA]</td>
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<tr>
<td>Quetiapine-DRLA [RZ]</td>
<td>Quetiapine GH 300 [GQ]</td>
</tr>
<tr>
<td>Quetiapine RBX [RA]</td>
<td>Quetiapine Sandoz [SZ]</td>
</tr>
<tr>
<td>Seroquel [AP]</td>
<td>Syquet [AF]</td>
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<td>Terry White Chemists Quetiapine [TW]</td>
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quetiapine 200 mg modified release tablet, 60

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>APO-Quetiapine XR [TX]</td>
<td>QUETIAPINE-AS XR [RW]</td>
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quetiapine 300 mg modified release tablet, 60

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<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>APO-Quetiapine XR [TX]</td>
<td>QUETIAPINE-AS XR [RW]</td>
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<tr>
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<td>Tevatiapine XR [TB]</td>
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quetiapine 150 mg modified release tablet, 60

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<tr>
<td>QUEPINE XR [RW]</td>
<td>Seroquel XR [AP]</td>
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<td>Tevatiapine XR [TB]</td>
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quetiapine 200 mg tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Quetiapine [TX]</td>
<td>Chem mart Quetiapine [CH]</td>
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<td>Delucon 200 [DO]</td>
<td>Kaptan [ER]</td>
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<td>Pharmacor Quetiapine 200 [CR]</td>
<td>Quetia 200 [RW]</td>
</tr>
<tr>
<td>Quetiapine Actavis 200 [ED]</td>
<td>Quetiapine AN [EA]</td>
</tr>
<tr>
<td>Quetiapine-DRLA [RZ]</td>
<td>Quetiapine GH 200 [GQ]</td>
</tr>
<tr>
<td>Quetiapine RBX [RA]</td>
<td>Quetiapine Sandoz [SZ]</td>
</tr>
<tr>
<td>Seroquel [AP]</td>
<td>Syquet [AF]</td>
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<tr>
<td>Terry White Chemists Quetiapine [TW]</td>
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</table>
NERVOUS SYSTEM

quetiapine 400 mg modified release tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>* APO-Quetiapine XR [TX]</td>
<td>* QUETIAPINE-AS XR [RW]</td>
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<tr>
<td>* Seroquel XR [AP]</td>
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quetiapine 50 mg modified release tablet, 60

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<td>* Seroquel XR [AP]</td>
<td>* Tevatiapine XR [TB]</td>
</tr>
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</table>

**QUETIAPINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

4391

Schizophrenia

Clinical criteria:
- The treatment must be for dose titration purposes.

4396

Acute mania

Clinical criteria:
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be for dose titration purposes.

4385

Bipolar I disorder

Clinical criteria:
- The treatment must be maintenance therapy, **AND**
- The treatment must be for dose titration purposes.

quetiapine 25 mg tablet, 60

<table>
<thead>
<tr>
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<td>* Quetiapine GH 25 [GQ]</td>
<td>* Quetiapine RBX [RA]</td>
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<td>* Quetiapine Sandoz [SZ]</td>
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<td>* Syquet [AF]</td>
<td>* Terry White Chemists</td>
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<td>Quetiapine [TW]</td>
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**Benzamides**

**AMISULPRIDE**

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

4246

Schizophrenia

amisulpride 400 mg tablet, 60

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<td>* Amisulpride 400 Winthrop</td>
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<td>* [WA]</td>
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<tr>
<td>* APO-Amisulpride [TX]</td>
<td>* Amisulpride Sandoz [SZ]</td>
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<tr>
<td>* Sulprix [AF]</td>
<td>* Solian 400 [SW]</td>
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### NERVOUS SYSTEM

**amisulpride 100 mg/mL oral liquid, 60 mL**

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**amisulpride 100 mg tablet, 30**

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<td>Solian 100 [SW]</td>
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**amisulpride 200 mg tablet, 60**

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<td>Solian 200 [SW]</td>
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**Other antipsychotics**

- **ARIPIPRAZOLE**
  
  **Note Shared Care Model:**
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Authority required (STREAMLINED)**

  4246

  Schizophrenia

  **aripiprazole 20 mg tablet, 30**

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<td>Abyraz [AF]</td>
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<td></td>
<td>Aripiprazole AN [EA]</td>
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<td>Aripiprazole GH [GQ]</td>
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<td>Abyraz [AF]</td>
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<td>Abyraz [AF]</td>
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<td>Aripiprazole AN [EA]</td>
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<td>Aripiprazole Sandoz [SZ]</td>
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</tbody>
</table>

  **aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (6) inert substance diluent [1 vial], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>MRVSN $</th>
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  **aripiprazole 15 mg tablet, 30**

<table>
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<th>Brand Name and Manufacturer</th>
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<td>Abyraz [AF]</td>
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<td>Aripiprazole AN [EA]</td>
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<td></td>
<td></td>
<td>Aripiprazole Sandoz [SZ]</td>
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</tbody>
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  **aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (6) inert substance diluent [1 vial], 1 pack**

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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</tbody>
</table>

- **BREXPIPRAZOLE**
  
  **Note Shared Care Model:**
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### brexpiprazole 2 mg tablet, 30

<table>
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<th>4246</th>
<th>Schizophrenia</th>
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</thead>
<tbody>
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<td>11188W</td>
<td>Max.Qty Packs</td>
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<td>NP</td>
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### brexpiprazole 4 mg tablet, 30

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### brexpiprazole 3 mg tablet, 30

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### brexpiprazole 1 mg tablet, 30

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<tr>
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</table>

### PALIPERIDONE

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
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### paliperidone 9 mg modified release tablet, 28

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<tbody>
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### paliperidone 150 mg modified release injection, 1 syringe

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<td>paliperidone 150 mg modified release injection, 1 syringe</td>
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### paliperidone 50 mg modified release injection, 1 syringe

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### paliperidone 6 mg modified release tablet, 28

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### paliperidone 75 mg modified release injection, 1 syringe

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### paliperidone 100 mg modified release injection, 1 syringe

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### paliperidone 3 mg modified release tablet, 28

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### PALIPERIDONE

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

### Authority required (STREAMLINED)

**6832**

Schizophrenia

**Clinical criteria:**
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

---

### Paliperidone

**paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe**

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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<td>..</td>
<td>1003.94</td>
<td>Invega Trinza [JC]</td>
</tr>
</tbody>
</table>

**paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe**

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</table>

**paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe**

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**paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe**

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### Risperidone

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

**6426**

Schizophrenia

### Authority required (STREAMLINED)

**5907**

Acute mania

**Clinical criteria:**
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

### Risperidone 3 mg tablet, 60

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<td></td>
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### Risperidone 1 mg/mL oral liquid, 100 mL

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### NERVOUS SYSTEM

#### Risperidone

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6897**
Severe behavioural disturbances

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

**6938**
Severe behavioural disturbances

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

#### Risperidone

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#### Risperidone

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#### Risperidone

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4246**
Schizophrenia

**Authority required (STREAMLINED)**

**5912**

**Bipolar I disorder**

**Clinical criteria:**
- The condition must be refractory to treatment, AND
- The treatment must be in combination with lithium or sodium valproate, AND
- The treatment must be maintenance therapy.

**risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

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Risperdal Consta [JC]

**risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

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Risperdal Consta [JC]

**risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

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Risperdal Consta [JC]

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**RISPERIDONE**

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**5903**

**Schizophrenia**

**risperidone 500 microgram tablet, 60**

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* Rispericor 0.5 [CR]  
* Risperidone Sandoz [SZ]  
* Rixadone [AF]  
* Risperidone AMNEAL [EF]  
* Rispernia [ER]  
* Risperidone [RW]  
* APO-Risperidone [TX]  
* Risperdal [JC]

**risperidone 500 microgram tablet, 20**

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**RISPERIDONE**

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**5993**

**Behavioural disturbances**

**Clinical criteria:**
- The condition must be characterised by psychotic symptoms and aggression, AND
- Patient must have dementia of the Alzheimer type, AND
- Patient must have failed to respond to non-pharmacological methods of treatment, AND
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required (STREAMLINED)**

**6897**

**Severe behavioural disturbances**

**Clinical criteria:**
- Patient must have autism spectrum disorder, AND
- The treatment must be under the supervision of a paediatrician or psychiatrist, AND
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

---

NERVOUS SYSTEM

---
• Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

6938
Severe behavioural disturbances
Treatment Phase: Continuing treatment

**Clinical criteria:**

• Patient must have autism spectrum disorder, **AND**

• Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**

• The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

• The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

• Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

---

**RISPERIDONE**

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

6010
Behavioural disturbances

**Clinical criteria:**

• The condition must be characterised by psychotic symptoms and aggression, **AND**

• Patient must have dementia of the Alzheimer type, **AND**

• Patient must have failed to respond to non-pharmacological methods of treatment, **AND**

• The treatment must be limited to a maximum duration of 12 weeks.

**Authority required (STREAMLINED)**

6898
Severe behavioural disturbances

**Clinical criteria:**

• Patient must have autism spectrum disorder, **AND**

• The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

• The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

• Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

6899
Severe behavioural disturbances
NERVOUS SYSTEM

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have autism spectrum disorder, AND
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, AND
- The treatment must be under the supervision of a paediatrician or psychiatrist, AND
- The treatment must be in combination with non-pharmacological measures.

Population criteria:
- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

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### risperidone 500 microgram tablet, 20

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<td>* Risperdal [JC]</td>
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</table>

### ANXIOLYTICS

#### Benzodiazepine derivatives

- **ALPRAZOLAM**

  **Note** The panic disorder must not be attributable to some known organic factor.
  **Note** No increase in the maximum number of repeats may be authorised.

  Authority required
  Panic disorder

  Clinical criteria:
  - The treatment must be for use when other treatments have failed; OR
  - The treatment must be for use when other treatments are inappropriate.

- **alprazolam 250 microgram tablet, 50**

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- **ALPRAZOLAM**

  **Note** Pharmaceutical benefits that have the form alprazolam tablet 1 mg are equivalent for the purposes of substitution.
  **Note** The panic disorder must not be attributable to some known organic factor.
  **Note** No increase in the maximum number of repeats may be authorised.

  Authority required
  Panic disorder

  Clinical criteria:
  - The treatment must be for use when other treatments have failed; OR
  - The treatment must be for use when other treatments are inappropriate.

- **alprazolam 1 mg tablet, 50**

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- **alprazolam 1 mg tablet, 10**

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- **ALPRAZOLAM**

  **Note** Pharmaceutical benefits that have the form alprazolam tablet 500 micrograms are equivalent for the purposes of substitution.
  **Note** The panic disorder must not be attributable to some known organic factor.
  **Note** No increase in the maximum number of repeats may be authorised.

  Authority required
  Panic disorder

  Clinical criteria:
  - The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

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### DIAZEPAM

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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Valpam 2 [RW]</td>
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</tbody>
</table>

### DIAZEPAM

**Authority required**

**Population criteria:**
- Patient must be under 18 years of age.

#### diazepam 1 mg/mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>2669L</td>
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<td>42.95</td>
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### DIAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months’ treatment (i.e. one month’s treatment with five repeats) may be requested.

#### diazepam 5 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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#### diazepam 2 mg tablet, 50

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<td>Valpam 2 [RW]</td>
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### DIAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a

---

General Pharmaceutical Benefits 629
disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

**Note** Up to six months’ treatment (i.e. one month’s treatment with five repeats) may be requested.

---

### diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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### OXAZEPAM

#### oxazepam 30 mg tablet, 25

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**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of oxazepam below.

---

#### oxazepam 15 mg tablet, 25

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</table>

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of oxazepam below.

---

### OXAZEPAM

#### Authority required

Malignant neoplasia (late stage)

**Authority required**

**Clinical criteria:**
- Patient must be receiving this drug for the management of anxiety, AND
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

**Clinical criteria:**
- Patient must be receiving this drug for the management of anxiety, AND
- Patient must be receiving long-term nursing care, AND
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

---

#### oxazepam 30 mg tablet, 25

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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#### oxazepam 15 mg tablet, 25

<table>
<thead>
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<th>No. of Rpts</th>
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#### oxazepam 30 mg tablet, 25

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#### oxazepam 15 mg tablet, 25

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### General

630  Schedule of Pharmaceutical Benefits – November 2017
### HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**

#### NITRAZEPAM

**nitrazepam 5 mg tablet, 25**

<table>
<thead>
<tr>
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<td>.</td>
<td>12.70</td>
<td>13.91</td>
<td>* Alodom [AF]</td>
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</table>

#### NITRAZEPAM

*Note* Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of nitrazepam below.

**nitrazepam 5 mg tablet, 25**

<table>
<thead>
<tr>
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<td>12.70</td>
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<td>* Alodom [AF]</td>
</tr>
</tbody>
</table>

#### NITRAZEPAM

*Note* Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

- Myoclonic epilepsy
- Malignant neoplasia (late stage)

**Authority required**

- Insomnia
  - Clinical criteria:
    - Patient must be receiving this drug for the management of insomnia, AND
    - Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND
    - Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

- Insomnia
  - Clinical criteria:
    - Patient must be receiving this drug for the management of insomnia, AND
    - Patient must be receiving long-term nursing care, AND
    - Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND
    - Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>5</td>
<td>*14.31</td>
<td>15.52</td>
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#### TEMAZEPAM

**temazepam 10 mg tablet, 25**

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<tr>
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<th>Premium $</th>
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<td>12.17</td>
<td>13.38</td>
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#### TEMAZEPAM

*Note* Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of temazepam.

**temazepam 10 mg tablet, 25**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>* APO-Temazepam [TX]</td>
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</table>

---

**General Pharmaceutical Benefits**

631
### TEMAZEPAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
- Malignant neoplasia (late stage)

**Authority required**
- Insomnia

**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**
- Insomnia

**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

---

**temazepam 10 mg tablet, 25**

<table>
<thead>
<tr>
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<td>14.46</td>
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</table>

---

### PSYCHOANALEPTICS

#### ANTIDEPRESSANTS

**Non-selective monoamine reuptake inhibitors**

### AMITRIPTYLINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**amitriptyline hydrochloride 50 mg tablet, 50**

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**amitriptyline hydrochloride 10 mg tablet, 50**

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**amitriptyline hydrochloride 25 mg tablet, 50**

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NERVOUS SYSTEM

- CLOMIPRAMINE
  Note Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
  patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse
  Practitioners.

  Restricted benefit
  Cataplexy
  Clinical criteria:
  - The condition must be associated with narcolepsy.

  Restricted benefit
  Obsessive-compulsive disorder
  Restricted benefit
  Phobic disorders

  Population criteria:
  - Patient must be an adult.

  clomipramine hydrochloride 25 mg tablet, 50
  1561E

<table>
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- DOTHIEPIN
  Note Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
  patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse
  Practitioners.

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  1357K

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  dothiepin hydrochloride 75 mg tablet, 30
  1358L

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<td>14.87</td>
<td>Dothep 75 [AF]</td>
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- DOXEPIN
  Note Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
  patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse
  Practitioners.

  doxepin 50 mg tablet, 50
  1012G

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  doxepin 25 mg capsule, 50
  1013H

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<td>21.09</td>
<td>15.30</td>
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  doxepin 10 mg capsule, 50
  1011F

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</table>

- IMIPRAMINE
  Note Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
  patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse
  Practitioners.

  imipramine hydrochloride 10 mg tablet, 50
  2420J

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imipramine hydrochloride 25 mg tablet, 50

NORTRIPTYLINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Major depression
Clinical criteria:
• The treatment must be for use when other anti-depressant therapy has failed.

Restricted benefit
Major depression
Clinical criteria:
• The treatment must be for use when other anti-depressant therapy is contraindicated.

Selective serotonin reuptake inhibitors

CITALOPRAM

Restricted benefit
Major depressive disorders

citalopram 10 mg tablet, 28

citalopram 20 mg tablet, 28

citalopram 40 mg tablet, 28

ESCITALOPRAM

Restricted benefit
Major depressive disorders

escitalopram 20 mg tablet, 28
ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:
• The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
• Patient must not have responded to non-pharmacological therapy, AND
• Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:
• The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
• Patient must not have responded to non-pharmacological therapy, AND
• Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:
• The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
• Patient must not have responded to non-pharmacological therapy, AND
• Patient must have been assessed by a psychiatrist.

ESCITALOPRAM

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:
• The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
• Patient must not have responded to non-pharmacological therapy, AND
• Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**
Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**
• The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
• Patient must not have responded to non-pharmacological therapy, AND
• Patient must have been assessed by a psychiatrist.

**Restricted benefit**
Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**
• The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
• Patient must not have responded to non-pharmacological therapy, AND
• Patient must have been assessed by a psychiatrist.

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**escitalopram 20 mg/mL oral liquid, 15 mL**

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<td>Lexapro [LU]</td>
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**FLUOXETINE**

**Restricted benefit**
Major depressive disorders

**Restricted benefit**
Obsessive-compulsive disorder

**fluoxetine 20 mg capsule, 28**

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<tbody>
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<td>FLUOTEX [RF]</td>
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<td>Fluoxetine-AN [ED]</td>
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<td>Fluoxetine Sandoz [SZ]</td>
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<td>Zactin [AF]</td>
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<tr>
<td>Auscap Aspen [RW]</td>
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<td>Chem mart Fluoxetine [CH]</td>
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<td>Fluoxetine AN [EA]</td>
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<td>Fluoxetine generichealth [GQ]</td>
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<td>GenRx Fluoxetine [GX]</td>
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**fluoxetine 20 mg dispersible tablet, 28**

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**FLUOXAMINE**

**Restricted benefit**
Major depressive disorders

**Restricted benefit**
Obsessive-compulsive disorder

**fluvoxamine maleate 50 mg tablet, 30**

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<tr>
<td>Voxam [SZ]</td>
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<td>Luvox [GO]</td>
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### NERVOUS SYSTEM

**fluvoxamine maleate 100 mg tablet, 30**

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**PAROXETINE**

- **Restricted benefit**
- Major depressive disorders
- **Restricted benefit**
- Obsessive-compulsive disorder
- **Restricted benefit**
- Panic disorder

**paroxetine 20 mg tablet, 30**

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**SERTRALINE**

- **Restricted benefit**
- Major depressive disorders

**sertraline 50 mg tablet, 30**

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**sertraline 100 mg tablet, 30**

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**SERTRALINE**

- **Restricted benefit**
- Obsessive-compulsive disorder
- **Restricted benefit**
- Panic disorder

- **Clinical criteria:**
  - The treatment must be for use when other treatments have failed; OR
  - The treatment must be for use when other treatments are inappropriate.

**sertraline 50 mg tablet, 30**

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**sertraline 100 mg tablet, 30**

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**General Pharmaceutical Benefits**
NERVOUS SYSTEM

Monoamine oxidase inhibitors, non-selective

**PHENELZINE**

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

**Depression**

**Clinical criteria:**
- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

**phenelzine 15 mg tablet, 100**

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**TRANYLCYPROMINE**

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**tranylcypromine 10 mg tablet, 50**

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**Monoamine oxidase A inhibitors**

**MOCLOBEMIDE**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

**Major depressive disorders**

**moclobemide 300 mg tablet, 60**

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<td>* GenRx Moclobemide [GX]</td>
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**moclobemide 150 mg tablet, 60**

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</table>

**Other antidepressants**

**DESVENLAFAXINE**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

**Major depressive disorders**

**desvenlafaxine 100 mg modified release tablet, 28**

<table>
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<th>No. of Rpts</th>
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<td>* Desvenlafaxine Actavis [EA]</td>
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<td>* Desvenlafaxine Sandoz [SZ]</td>
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* Sertraline AN [EA]
* Zoloft [PF]
### NERVOUS SYSTEM

**desvenlafaxine 100 mg modified release tablet, 28**

<table>
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<th>Max Qty Packs</th>
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**desvenlafaxine 100 mg modified release tablet, 28**

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9367B</td>
<td>1</td>
<td>5</td>
<td>28.61</td>
<td>29.82</td>
<td>* Pristiq [PF]</td>
</tr>
</tbody>
</table>

**desvenlafaxine 50 mg modified release tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10234P</td>
<td>1</td>
<td>5</td>
<td>25.36</td>
<td>26.57</td>
<td>* APO-Desvenlafaxine MR [TX] * Desvenlafaxine GH XR [GQ]</td>
</tr>
</tbody>
</table>

**desvenlafaxine 50 mg modified release tablet, 28**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
</table>

**desvenlafaxine 50 mg modified release tablet, 28**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9366Y</td>
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<td>5</td>
<td>25.36</td>
<td>26.57</td>
<td>* Pristiq [PF]</td>
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</table>

### DULOXETINE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Major depressive disorders

**duloxetine 60 mg enteric capsule, 28**

<table>
<thead>
<tr>
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<tr>
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<td>17.01</td>
<td>18.22</td>
<td>* Andepra [EL] * Chem mart Duloxetine [CH] * Duloxetine AN [EA] * DYTREX 60 [RW] * Terry White Chemists Duloxetine [TW]</td>
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**duloxetine 30 mg enteric capsule, 28**

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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</table>

**LITHIUM CARBONATE**

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**lithium carbonate 250 mg tablet, 200**

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<tr>
<td>3059B</td>
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<td>24.40</td>
<td>Lithicarb [AS]</td>
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**lithium carbonate 450 mg modified release tablet, 100**

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<tr>
<td>8290H</td>
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<td>Quilonum SR [AS]</td>
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</table>

### MIANSERIN

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Severe depression

**mianserin hydrochloride 20 mg tablet, 50**

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<tr>
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<tr>
<td>1</td>
<td>5</td>
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**mianserin hydrochloride 10 mg tablet, 50**

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<td>18.89</td>
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<td>Lumin 10 [AF]</td>
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**MIRTAZAPINE**

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**mirtazapine 30 mg tablet, 30**

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<th>No. of Rpts</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>14.69</td>
<td>15.90</td>
<td></td>
<td>* APO-Mirtazapine [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Aurozepine 30 [DO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Chem mart Mirtzapine [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mirtazapine AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mirtazapine Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
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<td>Mirtzapine [TW]</td>
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**mirtazapine 45 mg tablet, 30**

<table>
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<tr>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Aurozepine 45 [DO]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Chem mart Mirtzapine [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mirtazapine AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
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**MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30**

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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>16.61</td>
<td>17.82</td>
<td></td>
<td>* Milivin OD 30 [DO]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mirtazapine Sandoz ODT 30 [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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**MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30**

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<tr>
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<td>15.23</td>
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<td></td>
<td></td>
<td></td>
<td>* Mirtazapine Sandoz ODT 15 [SZ]</td>
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<td></td>
<td></td>
<td></td>
<td>* Mirtazapine AN ODT [EA]</td>
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**mirtazapine 15 mg tablet, 30**

<table>
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<th>Packs</th>
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<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>19.98</td>
<td>20.64</td>
<td></td>
<td>* Aurozepine 15 [DO]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Chem mart Mirtzapine [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Mirtazapine AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mirtazapine Sandoz [SZ]</td>
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</table>

**MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30**

<table>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>19.39</td>
<td>20.60</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
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<td>* Mirtazapine Sandoz ODT 45 [SZ]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mirtazapine AN ODT [EA]</td>
</tr>
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**REBOXETINE**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**REBOXETINE 4 mg tablet, 60**

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<tr>
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<td>..</td>
<td>37.80</td>
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<td>Edronax [PF]</td>
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**VENLAFAXINE**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Major depressive disorders

**VENLAFAXINE 150 mg modified release capsule, 28**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<tr>
<td>8302Y</td>
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<td>..</td>
<td>15.48</td>
<td>16.69</td>
<td>* APO-Venlafaxine XR [TX]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Chem mart Venlafaxine XR</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>[CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Elaxine SR 150 [ZP]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>* Sandoz Venlafaxine XR [HX]</td>
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<td></td>
<td></td>
<td></td>
<td>* Venlafaxine AN SR [EA]</td>
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<td>* Venlafaxine Sandoz XR [SZ]</td>
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<table>
<thead>
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<td></td>
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<td>[CH]</td>
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<td>* Elaxine SR 75 [ZP]</td>
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<td>* Sandoz Venlafaxine XR [HX]</td>
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<td></td>
<td></td>
<td></td>
<td>* Venlafaxine AN SR [EA]</td>
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<td>* Venlafaxine Sandoz XR [SZ]</td>
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<table>
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<tr>
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<td>8868R</td>
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<td>* Efexor-XR [PF]</td>
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<td></td>
<td>* Venlafaxine AN SR [EA]</td>
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**VENLAFAXINE 75 mg modified release capsule, 28**

**VENLAFAXINE 37.5 mg modified release capsule, 28**

**PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS**

**Centrally acting sympathomimetics**

**ARMODAFINIL**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or modafinil.

**Authority required**
Narcolepsy
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by a qualified sleep medicine practitioner or neurologist.
NERVOUS SYSTEM

Clinical criteria:
- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, AND
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, AND
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:
(a) a psychiatric disorder;
(b) a cardiovascular disorder;
(c) a history of substance abuse;
(d) glaucoma;
(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:
(a) a completed authority prescription form; and
(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
(c) details of the contraindication or intolerance to dexamphetamine sulfate; and
(d) either:
(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

armodafinil 50 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10922W</td>
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<td>Nuvigil [TB]</td>
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armodafinil 150 mg tablet, 30

<table>
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<td>Nuvigil [TB]</td>
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armodafinil 250 mg tablet, 30

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ATOMOXETINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4578
Attention deficit hyperactivity disorder
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug.

Authority required (STREAMLINED)

6279
Attention deficit hyperactivity disorder
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, AND
- Patient must have a contraindication to dexamphetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
• Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
• Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
• Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**
• Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**atomoxetine 10 mg capsule, 28**

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**ATOMOXETINE**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6279**
Attention deficit hyperactivity disorder
Treatment Phase: Initial treatment

**Clinical criteria:**
• The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, AND
• Patient must have a contraindication to dexamphetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
• Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
• Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
• Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**
• Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Authority required (STREAMLINED)**

**4578**
Attention deficit hyperactivity disorder
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have previously been issued with an authority prescription for this drug.

**atomoxetine 25 mg capsule, 28**

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**atomoxetine 80 mg capsule, 28**

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**atomoxetine 18 mg capsule, 28**

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**atomoxetine 40 mg capsule, 28**

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**atomoxetine 60 mg capsule, 28**

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NERVOS SYSTEM

**atomoxetine 100 mg capsule, 28**

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**DEXAMFETAMINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

**Authority required**

Narcolepsy

**dexamfetamine sulfate 5 mg tablet, 100**

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**LISDEXAMFETAMINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must require continuous coverage over 12 hours.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**lisdexamfetamine dimesilate 50 mg capsule, 30**

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**lisdexamfetamine dimesilate 70 mg capsule, 30**

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**lisdexamfetamine dimesilate 30 mg capsule, 30**

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**METHYLPHENIDATE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Attention deficit hyperactivity disorder

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours.
methylphenidate hydrochloride 18 mg modified release tablet, 30

<table>
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methylphenidate hydrochloride 27 mg modified release tablet, 30

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methylphenidate hydrochloride 36 mg modified release tablet, 30

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methylphenidate hydrochloride 54 mg modified release tablet, 30

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**METHYLPHENIDATE**

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Attention deficit hyperactivity disorder

**Population criteria:**
- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**
- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours.

methylphenidate hydrochloride 40 mg modified release capsule, 30

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methylphenidate hydrochloride 20 mg modified release capsule, 30

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methylphenidate hydrochloride 30 mg modified release capsule, 30

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methylphenidate hydrochloride 10 mg modified release capsule, 30

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**METHYLPHENIDATE**

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Attention deficit hyperactivity disorder

**Treatment must be in accordance with the law of the relevant State or Territory.**

methylphenidate hydrochloride 10 mg tablet, 100

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**MODAFINIL**

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
General

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or armodafinil.

Authority required
Narcolepsy
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:
- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, AND
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, AND
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:
(a) a psychiatric disorder;
(b) a cardiovascular disorder;
(c) a history of substance abuse;
(d) glaucoma;
(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:
(a) a completed authority prescription form; and
(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
(c) details of the contraindication or intolerance to dexamphetamine sulfate; and
(d) either:
   (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
   (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required
Narcolepsy
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Note: Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### modafinil 100 mg tablet, 60

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### ANTI-DEMENTIA DRUGS

#### Anticholinesterases

- **DONEPEZIL**

  Note: Continuing Therapy Only:
  For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  Authority required (STREAMLINED)

  4219
  Mild to moderately severe Alzheimer disease
  Treatment Phase: Continuing

  Clinical criteria:
  - Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND
• Patient must demonstrate a clinically meaningful response to the initial treatment, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.
Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.
Clinically meaningful response to treatment is demonstrated in the following areas:
Patient's quality of life including but not limited to level of independence and happiness;
Patient's cognitive function including but not limited to memory, recognition and interest in environment;
Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**DONEPEZIL**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Mild to moderately severe Alzheimer disease

**Clinical criteria:**
- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, AND
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

**Authority required**
Mild to moderately severe Alzheimer disease

**Clinical criteria:**
- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.
NERVOS SYSTEM

GALANTAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

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Mild to moderately severe Alzheimer disease
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Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:
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- Patient's cognitive function including but not limited to memory, recognition and interest in environment;
- Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

galantamine 24 mg modified release capsule, 28

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Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
(4) Intellectual (developmental or acquired) disability, eg Down’s syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

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For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

donepezil hydrochloride 10 mg tablet, 28

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Authority required (STREAMLINED)

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Mild to moderately severe Alzheimer disease
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Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:
- Patient's quality of life including but not limited to level of independence and happiness;
- Patient's cognitive function including but not limited to memory, recognition and interest in environment;
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donepezil hydrochloride 5 mg tablet, 28

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Notes on page 648: Schedule of Pharmaceutical Benefits – November 2017
### NERVOUS SYSTEM

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### GALANTAMINE

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**Authority required**

**Mild to moderately severe Alzheimer disease**

**Treatment Phase: Initial**

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

**Mild to moderately severe Alzheimer disease**

**Treatment Phase: Initial**

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

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1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
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5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
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**galantamine 24 mg modified release capsule, 28**

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General Pharmaceutical Benefits
**NERVOUS SYSTEM**

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**RIVASTIGMINE**

*Note: Continuing Therapy Only:*

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**Authority required (STREAMLINED)**

**4219**

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
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### rivastigmine 4.6 mg/24 hours patch, 30

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### rivastigmine 4.5 mg capsule, 56

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### rivastigmine 1.5 mg capsule, 56

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<th>Max.Qty Packs</th>
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* * Reminyl [JC]
RIVASTIGMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial
Clinical criteria:
• Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, AND
• The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial
Clinical criteria:
• Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND
• The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who qualify under this criterion are from 1 or more of the following groups:
(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Rivastigmine 4.6 mg/24 hours patch, 30

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Rivastigmine 4.5 mg capsule, 56

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Rivastigmine 9.5 mg/24 hours patch, 30

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Rivastigmine 3 mg capsule, 56

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</table>
**MEMANTINE**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

Moderately severe Alzheimer disease  
Treatment Phase: Continuing  
Clinical criteria:  
- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**  
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**  
- The treatment must be the sole PBS-subsidised therapy for this condition.  
Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.  
Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.  
Clinically meaningful response to treatment is demonstrated in the following areas:  
- Patient's quality of life including but not limited to level of independence and happiness;  
- Patient's cognitive function including but not limited to memory, recognition and interest in environment;  
- Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

memantine hydrochloride 20 mg tablet, 28

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<td>Memantine generichealth [GQ]</td>
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memantine hydrochloride 10 mg tablet, 56

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**MEMANTINE**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Moderately severe Alzheimer disease  
Treatment Phase: Initial  
Clinical criteria:  
- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**  
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**  
- The treatment must be the sole PBS-subsidised therapy for this condition.  
The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.  
The application must be made in writing, but initial supply may be sought by telephone.  
For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. **Authority required**

**Moderately severe Alzheimer disease**

**Treatment Phase: Initial**

**Clinical criteria:**
- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:
1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
4. Intellectual (developmental or acquired) disability, eg Down's syndrome;
5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
6. Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

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### OTHER NERVOUS SYSTEM DRUGS

#### PARASYMPATHOMIMETICS

##### Anticholinesterases

**PYRIDOSTIGMINE**

**PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50**

**PYRIDOSTIGMINE BROMIDE Tablet 60 mg, 150**

**PYRIDOSTIGMINE BROMIDE 180 mg modified release tablet, 50**

**Choline esters**

**BETHANECHOL**

**bethanechol chloride 10 mg tablet, 100**
NERVOUS SYSTEM

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

**BUPROPION**

*Note* Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

*Note* The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

*6881*

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**bupropion hydrochloride 150 mg modified release tablet, 90**

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**BUPROPION**

*Note* Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

*Note* The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

*Note* A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

*6882*

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**bupropion hydrochloride 150 mg modified release tablet, 30**

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<th>Max.Qty</th>
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<td>Zyban [AS]</td>
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</table>

**NICOTINE**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotine dependence

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**Nicotine 21 mg/24 hours patch, 28**

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<th>Max Qty Packs</th>
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**Nicotine 14 mg/24 hours patch, 28**

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**Nicotine 7 mg/24 hours patch, 28**

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<td>38.80</td>
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</table>

**Nicotine**

- **Note**: Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

- **Note**: No increase in the maximum quantity or number of units may be authorised.

- **Note**: No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotinell Step 1

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Nicotine 21 mg/24 hours patch, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**Nicotine**

- **Note**: No increase in the maximum quantity or number of units may be authorised.

- **Note**: No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Nicotinell Step 1

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Nickel by patch, 28**

**Note**: Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Restricted benefit**

Nicotinell Step 1

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**
- The treatment must be as an aid to achieving abstinence from smoking, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have indicated they are ready to cease smoking, AND
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

**Treatment criteria:**
- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**Nicotine 21 mg/24 hours patch, 28**

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**Nicotine 25 mg/16 hours patch, 28**

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</table>

**Varenicline**

- **Note**: A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
NERVOUS SYSTEM

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6885
Nicotine dependence
Treatment Phase: Completion of a short-term (24 weeks) course of treatment

Clinical criteria:
• The treatment must be as an aid to achieving abstinence from smoking, AND
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, AND
• Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

Treatment criteria:
• Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

5469W

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VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6864
Nicotine dependence
Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:
• The treatment must be as an aid to achieving abstinence from smoking, AND
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment.

Treatment criteria:
• Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

9129L

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<td>*208.61</td>
<td>38.80</td>
<td></td>
<td>Champix [PF]</td>
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</table>

VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6871
Nicotine dependence
Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:
• The treatment must be as an aid to achieving abstinence from smoking, AND
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have indicated they are ready to cease smoking, AND
• Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:
• Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.
Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53**

<table>
<thead>
<tr>
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<th>No of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
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<td></td>
<td>94.60</td>
<td>38.80</td>
<td>Champix [PF]</td>
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</table>

**Drugs used in alcohol dependence**

### ACAMPROSATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**5366**

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**acamprosate calcium 333 mg enteric tablet, 180**

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</table>

### NALTREXONE

Caution Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Authority required**

**Alcohol dependence**

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**naltrexone hydrochloride 50 mg tablet, 30**

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<td></td>
<td>* ReVia [BQ]</td>
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<td></td>
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<td></td>
<td>* Naltrexone GH [GQ]</td>
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**OTHER NERVOUS SYSTEM DRUGS**

**Other nervous system drugs**

### DIMETHYL FUMARATE

Note Special Pricing Arrangements apply.

**Authority required**

**Multiple sclerosis**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

<table>
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<tr>
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<tr>
<td>2</td>
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<td>*969.23</td>
<td>38.80</td>
<td>Tecfidera [BD]</td>
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</table>

### DIMETHYL FUMARATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

**Authority required**

**Multiple sclerosis**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 240 mg enteric capsule, 56

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**DIMETHYL FUMARATE**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

**Authority required**

Multiple sclerosis

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*969.23</td>
<td>38.80</td>
<td>Tecfidera [BD]</td>
</tr>
</tbody>
</table>

**RILUZOLE**

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed by a neurologist, AND
- Patient must not have had the disease for more than 5 years, AND
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, AND
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND
- Patient must not have undergone a tracheostomy, AND
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

**Authority required**

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND
- Patient must not have undergone a tracheostomy, AND
- Patient must not have experienced respiratory failure.

riluzole 50 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>203.32</td>
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<td>a APO-Riluzole [TX]</td>
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<td></td>
<td></td>
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<td>a Pharmacor Riluzole [CR]</td>
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</table>
### TETRABENAZINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
5340
Hyperkinetic extrapyramidal disorders

**tetrabenazine 25 mg tablet, 112**

<table>
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<td>338.60</td>
<td>38.80</td>
<td>iNova Pharmaceuticals (Australia) Pty Ltd [IA]</td>
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### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

### ANTIPROTOZOALS

**AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES**

**Other agents against amoebiasis and other protozoal diseases**

### ATOVAQUONE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
5609
Mild to moderate Pneumocystis carinii pneumonia

**atovaquone 750 mg/5 mL oral liquid, 210 mL**

<table>
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<tr>
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<td>976.85</td>
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### PYRIMETHAMINE

**pyrimethamine 25 mg tablet, 50**

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<td>19.32</td>
<td>20.53</td>
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<td>Daraprim [RW]</td>
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### ANTIMALARIALS

**Biguanides**

### ATOVAQUONE + PROGUANIL

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Confirmed or suspected Plasmodium falciparum malaria

**Population criteria:**
- Patient must be aged 3 years or older.
- Clinical criteria:
  - The treatment must be used where quinine containing regimens are inappropriate.

**atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12**

<table>
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### QUININE

**Caution** Severe thrombocytopenia has been reported with this drug.

**Authority required (STREAMLINED)**
5633  Malaria
quinine sulfate 300 mg tablet, 50
1975Y

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<td>Quinate [RW]</td>
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</table>

**Artemisinin and derivatives, combinations**

### ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**
Confirmed or suspected Plasmodium falciparum malaria

**Clinical criteria:**
- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

#### artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18
5296R

<table>
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<td>89.24</td>
<td>38.80</td>
<td></td>
<td>Riamet 20mg/120mg Dispersible [SZ]</td>
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</table>

### ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**
Confirmed or suspected Plasmodium falciparum malaria

#### artemether 20 mg + lumefantrine 120 mg tablet, 24
9498X

<table>
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<td>89.24</td>
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<td>Riamet [SZ]</td>
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### ANTHELMINTICS

#### ANTITREMATODALS

**Quinoline derivatives and related substances**

### PRAZIQUANTEL

**Authority required (STREAMLINED)**
5659

**Schistosomiasis**

#### praziquantel 600 mg tablet, 8
9447F

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### ANTINEMATODAL AGENTS

**Benzimidazole derivatives**

### ALBENDAZOLE

**Authority required (STREAMLINED)**
5607

**Hydatid disease**

**Clinical criteria:**
- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

#### albendazole 400 mg chewable tablet, 60
8459F

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### ALBENDAZOLE

**Authority required (STREAMLINED)**
5680

**Tapeworm infestation**

#### albendazole 200 mg chewable tablet, 6
8503M

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<td>Zentel [AS]</td>
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</table>
## ALBENDAZOLE

**Authority required (STREAMLINED)**

*5817*  
Whipworm infestation

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

*5712*  
Strongyloidiasis

**Authority required (STREAMLINED)**

*5797*  
Hookworm infestation

**albendazole 200 mg chewable tablet, 6**

<table>
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**Tetrahydropyrimidine derivatives**

## PYRANTEL

**pyrantel 250 mg tablet, 6**

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**pyrantel 125 mg tablet, 6**

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**Avermectins**

## IVERMECTIN

**Authority required (STREAMLINED)**

*4319*  
Onchocerciasis

**ivermectin 3 mg tablet, 4**

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<td>31.65</td>
<td>32.86</td>
<td>Stromectol [MK]</td>
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## IVERMECTIN

**Authority required (STREAMLINED)**

*4328*  
Strongyloidiasis

**Authority required (STREAMLINED)**

*4565*  
Crusted (Norwegian) scabies

**Clinical criteria:**
- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; **OR**
- Patient must have a contraindication to topical treatment.

**Population criteria:**
- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Authority required (STREAMLINED)**

*4566*  
Human sarcoptic scabies

**Clinical criteria:**
- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; **OR**
- Patient must have a contraindication to topical treatment.

**Population criteria:**
- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

**Note** This drug is not PBS-subsidised for first line treatment of typical scabies.
**ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS**

ECTOPARASITICIDES, INCL. SCABICIDES

*Pyrethrines, incl. synthetic compounds*

**PERMETHRIN**

permethrin 5% cream, 30 g

<table>
<thead>
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<td>1</td>
<td>..</td>
<td>19.64</td>
<td>20.85</td>
<td>Lyclear [JT]</td>
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</table>

**RESPIRATORY SYSTEM**

**NASAL PREPARATIONS**

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

*Other nasal preparations*

**MUPIROCIN**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Code</th>
<th>6647</th>
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</thead>
<tbody>
<tr>
<td>6647</td>
<td>Staphylococcus aureus infection</td>
</tr>
</tbody>
</table>

**Clinical criteria:**
- Patient must have nasal colonisation with the bacteria.

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**mupirocin 2% (20 mg/g) ointment, 3 g**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>22.84</td>
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<td>Bactroban [GK]</td>
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**DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

**ADRENERGICS, INHALANTS**

*Selective beta-2-adrenoreceptor agonists*

**EFORMOTEROL**

*Restricted benefit*

**Asthma**

**Clinical criteria:**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; **OR**
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>27.58</td>
<td>28.79</td>
<td>Oxis Turbuhaler [AP]</td>
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**eformoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>35.88</td>
<td>37.09</td>
<td>Oxis Turbuhaler [AP]</td>
</tr>
</tbody>
</table>

**INDACATEROL**

*Note* This drug is not PBS-subsidised for the treatment of asthma.

**Restricted benefit**

**Chronic obstructive pulmonary disease (COPD)**
SALBUTAMOL

**Salbutamol**

**Indications**
- Bronchospasm
- Asthma
- Chronic obstructive pulmonary disease (COPD)

**Clinical Criteria**
- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.
- Patient must experience frequent episodes of the condition, AND

**Note**
Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.
RESPIRATORY SYSTEM

- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>8141L</td>
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**TERBUTALINE**

terbutaline sulfate 500 microgram/actuation powder for inhalation, 100 actuations

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</table>

**BUDESONIDE + EFORMOTEROL**

Restricted benefit

Asthma

**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**
- Patient must be aged 12 years or over.

**budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

<table>
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<tr>
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**budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**BUDESONIDE + EFORMOTEROL**

Restricted benefit

Asthma

**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**
- Patient must be aged 12 years or over.

**budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations**

<table>
<thead>
<tr>
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**budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<td>38.80</td>
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</table>

**BUDESONIDE + EFORMOTEROL**

Restricted benefit

Asthma

**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.
Population criteria:
- Patient must be aged 12 years or over.

Note Symbicort 400/12 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Restricted benefit**
Chronic obstructive pulmonary disease (COPD)

Clinical criteria:
- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND
- The treatment must be for symptomatic treatment.

Note Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

**BUDESONIDE + EFOMOTEROL**

**Restricted benefit**
Asthma

Clinical criteria:
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:
- Patient must be aged 12 years or over.

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy as the approved Product Information does not specify such use.

**FLUTICASONE + EFOMOTEROL**

Note Flutiform is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

Note Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.
**FLUTICASONE + SALMETEROL**

**Reserved benefit**

### Asthma

**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
- Patient must be aged 4 years or older.

### Fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
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<td>flutiform 250/10 [MF]</td>
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</table>

### Fluticasone propionate 50 microgram/actuation + salmeterol fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
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<td>40.24</td>
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### Fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium</th>
<th>DPMQ</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>48.25</td>
<td>38.80</td>
<td>* Fluticasone + Salmeterol Cipla 125/25 [LR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* SalplusF Inhaler 125/25 [YC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Seretide MDI 125/25 [GK]</td>
</tr>
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</table>

### Fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
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<tbody>
<tr>
<td>1</td>
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<td>48.25</td>
<td>38.80</td>
<td>Seretide Accuhaler 250/50</td>
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</table>

### Fluticasone propionate 100 microgram/actuation + salmeterol 25 microgram/actuation powder for inhalation, 60 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
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<td>41.56</td>
<td>38.80</td>
<td>Seretide Accuhaler 100/50</td>
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### Fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<td>41.56</td>
<td>38.80</td>
<td>Seretide MDI 50/25 [GK]</td>
</tr>
</tbody>
</table>

### FLUTICASONE + SALMETEROL

**Reserved benefit**

### Asthma

**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
- Patient must be aged 4 years or older.

**Restricted benefit**

### Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**
- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note:**
- Patient must not be on a concomitant single agent long-acting beta-2 agonist.
- This product is not indicated for the initiation of bronchodilator therapy in COPD.

### Fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>1</td>
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<td>61.39</td>
<td>38.80</td>
<td>* Fluticasone + Salmeterol Cipla 250/25 [LR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* SalplusF Inhaler 250/25 [YC]</td>
</tr>
</tbody>
</table>
### FLUTICASONE Furoate + VILANTEROL

**Note** This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

#### FLUTICASONE Furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

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<tbody>
<tr>
<td>†1</td>
<td>5</td>
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<td>71.62</td>
<td>38.80</td>
<td>Breo Ellipta 200/25 [GK]</td>
</tr>
</tbody>
</table>

#### FLUTICASONE Furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>†1</td>
<td>5</td>
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<td>56.12</td>
<td>38.80</td>
<td>Breo Ellipta 100/25 [GK]</td>
</tr>
</tbody>
</table>

### Aclidinium + Eformoterol

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

#### Aclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation powder for, 60 actuations

<table>
<thead>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>†1</td>
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<td>..</td>
<td>91.18</td>
<td>38.80</td>
<td>Brimica Genuair [FK]</td>
</tr>
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</table>
### INDACATEROL + GLYCOPYRRONIUM

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

### TIOTROPIUM + OLODATEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

### UMECLIDINIUM + VILANTEROL

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

### OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

#### Glucocorticoids

**BECLOMETASONE**

beclometasone dipropionate 100 microgram/actuation pressurised inhalation, 200 actuations

beclometasone dipropionate 50 microgram/actuation pressurised inhalation, 200 actuations
• Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

**BECLOMETHASONE DIPROPIONATE** Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<td>38.11</td>
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<td>Qvar 100 Autohaler [IA]</td>
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</table>

**BECLOMETHASONE DIPROPIONATE** Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1

<table>
<thead>
<tr>
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</table>

**BUDESONIDE**

budesonide 400 microgram/actuation powder for inhalation, 200 actuations

<table>
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<tbody>
<tr>
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<td>5</td>
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<td>44.27</td>
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<td>Pulmicort Turbuhaler [AP]</td>
</tr>
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budesonide 100 microgram/actuation powder for inhalation, 200 actuations

<table>
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<td>26.28</td>
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budesonide 200 microgram/actuation powder for inhalation, 200 actuations

<table>
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<td>31.45</td>
<td>32.66</td>
<td>Pulmicort Turbuhaler [AP]</td>
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</table>

**BUDESONIDE**

Authority required (STREAMLINED)

6340

Severe chronic asthma

Clinical criteria:

• Patient must require long-term steroid therapy, AND
• Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
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<td>47.27</td>
<td>38.80</td>
<td>Pulmicort Respules [AP]</td>
</tr>
</tbody>
</table>

budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>37.07</td>
<td>38.28</td>
<td>Pulmicort Respules [AP]</td>
</tr>
</tbody>
</table>

**CICLESONIDE**

ciclesonide 160 microgram/actuation pressurised inhalation, 120 actuations

<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
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<td>40.85</td>
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<td>Alvesco 160 [AP]</td>
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ciclesonide 80 microgram/actuation pressurised inhalation, 120 actuations

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>Alvesco 80 [AP]</td>
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</table>

**FLUTICASONE**

fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
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<td>18.50</td>
<td>19.71</td>
<td>Flixotide Junior Accuhaler [GK]</td>
</tr>
</tbody>
</table>

fluticasone propionate 50 microgram/actuation pressurised inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>18.50</td>
<td>19.71</td>
<td>Flixotide Junior [GK]</td>
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fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations

<table>
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<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>42.06</td>
<td>38.80</td>
<td>Flixotide Accuhaler [GK]</td>
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</tbody>
</table>
### General

#### RESPIRATORY SYSTEM

**fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations**

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>27.92</td>
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**fluticasone propionate 125 microgram/actuation pressurised inhalation, 120 actuations**

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<tbody>
<tr>
<td>‡1</td>
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<td>..</td>
<td>42.06</td>
<td>38.80</td>
<td>Fluticol Genuair [GK]</td>
</tr>
</tbody>
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**fluticasone propionate 250 microgram/actuation pressurised inhalation, 120 actuations**

<table>
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<th>Brand Name and Manufacturer</th>
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<td>‡1</td>
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<td>..</td>
<td>59.42</td>
<td>38.80</td>
<td>Spiriva Respimat [BY]</td>
</tr>
</tbody>
</table>

### Anticholinergics

#### Aclidinium

- **Aclidinium**
  - **Restricted benefit**
  - Chronic obstructive pulmonary disease (COPD)

**acldinium 322 microgram/actuation inhalation: powder for, 60 actuations**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>61.97</td>
<td>38.80</td>
<td>Bretaris Genuair [FK]</td>
</tr>
</tbody>
</table>

#### Glycopyrronium

- **Glycopyrronium**
  - **Restricted benefit**
  - Chronic obstructive pulmonary disease (COPD)

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>61.97</td>
<td>38.80</td>
<td>seebri breezhaler [NV]</td>
</tr>
</tbody>
</table>

#### Ipratropium

- **Ipratropium**
  - **Restricted benefit**
  - Asthma
  - Clinical criteria:
    - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>34.93</td>
<td>36.14</td>
<td>Atrovent [BY]</td>
</tr>
</tbody>
</table>

- **Ipratropium**
  - **Restricted benefit**
  - Chronic obstructive pulmonary disease (COPD)
  - Clinical criteria:
    - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>27.83</td>
<td>28.54</td>
<td>Aeron 250 [QA]</td>
</tr>
</tbody>
</table>

**Ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>30.77</td>
<td>31.48</td>
<td>Aeron 500 [QA]</td>
</tr>
</tbody>
</table>

#### Tiotropium

- **Tiotropium**
  - **Restricted benefit**
  - Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease
  - Treatment Phase: Long-term maintenance treatment

**Tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>59.42</td>
<td>38.80</td>
<td>Spiriva Respimat [BY]</td>
</tr>
</tbody>
</table>
### Tiotropium

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

Tiotropium 18 microgram powder for inhalation, 30 capsules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiriva [BY]</td>
<td>59.42</td>
<td>38.80</td>
<td></td>
</tr>
</tbody>
</table>

Note: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### Tiotropium

**Restricted benefit**

Severe asthma

Clinical criteria:
- Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid and a long acting beta-2 agonist.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

Tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spiriva Respimat [BY]</td>
<td>59.42</td>
<td>38.80</td>
<td></td>
</tr>
</tbody>
</table>

### Umeclidinium

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

Umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
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<tbody>
<tr>
<td>Incruse Ellipta [GK]</td>
<td>61.97</td>
<td>38.80</td>
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</table>

### Cromoglycate

Sodium cromoglycate 1 mg/actuation pressurised inhalation, 200 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>Intal CFC-Free [SW]</td>
<td>34.64</td>
<td>35.85</td>
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</table>

Sodium cromoglycate 5 mg/actuation pressurised inhalation, 112 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intal Forte CFC-Free [SW]</td>
<td>38.82</td>
<td>38.80</td>
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</table>

Sodium cromoglycate 20 mg powder for inhalation, 100 capsules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intal Spincaps [EA]</td>
<td>32.82</td>
<td>34.03</td>
<td></td>
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</table>

### Nedocromil

Nedocromil sodium 2 mg/actuation pressurised inhalation, 112 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
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<tbody>
<tr>
<td>Tilade CFC-Free [SW]</td>
<td>38.72</td>
<td>38.80</td>
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### Adrenergics for Systemic Use

**Alpha- and beta-adrenoceptor agonists**

### Adrenaline

Adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link Medical Products Pty Ltd [LM]</td>
<td>22.58</td>
<td>23.79</td>
<td></td>
</tr>
</tbody>
</table>
adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5004J</td>
<td></td>
<td></td>
<td>22.58</td>
<td>23.79</td>
<td>Link Medical Products Pty Ltd</td>
</tr>
</tbody>
</table>

**ADRENALINE**

Caution EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

Note No applications for repeats will be authorised.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

adrenaline 150 microgram/0.3 mL injection, 1 dose

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>8697R</td>
<td></td>
<td></td>
<td>97.10</td>
<td>38.80</td>
<td>EpiPen Jr. [AL]</td>
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</table>

adrenaline 300 microgram/0.3 mL injection, 1 dose

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<tr>
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<td>97.10</td>
<td>38.80</td>
<td>EpiPen [AL]</td>
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</table>

**Selective beta-2-adrenoreceptor agonists**

**SALBUTAMOL**

salbutamol 2 mg/5 mL oral liquid, 150 mL

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<tbody>
<tr>
<td>1103C</td>
<td></td>
<td></td>
<td>*24.81</td>
<td>26.02</td>
<td>Ventolin [GK]</td>
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</table>

**TERBUTALINE**

terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules

<table>
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<th>Max Qty Packs</th>
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<tr>
<td>1034K</td>
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<td></td>
<td>31.06</td>
<td>32.27</td>
<td>Bricanyl [AP]</td>
</tr>
</tbody>
</table>

**OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

**Xanthines**

**THEOPHYLLINE**

Caution Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Theophylline 300 mg modified release tablet, 100

<table>
<thead>
<tr>
<th>8231F</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>.</td>
<td>17.94</td>
<td>19.15</td>
<td>Nuelin-SR 300 [IA]</td>
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Theophylline 200 mg modified release tablet, 100

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<th>8230E</th>
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<tr>
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<td>5</td>
<td>.</td>
<td>15.83</td>
<td>17.04</td>
<td>Nuelin-SR 200 [IA]</td>
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</table>

Theophylline 133.3 mg/25 mL oral liquid, 500 mL

<table>
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<th>2614N</th>
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<td>16.68</td>
<td>17.89</td>
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Theophylline 250 mg modified release tablet, 100

<table>
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<tr>
<th>2634P</th>
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<td>5</td>
<td>.</td>
<td>16.79</td>
<td>18.00</td>
<td>Nuelin-SR 250 [IA]</td>
</tr>
</tbody>
</table>

Leukotriene receptor antagonists

**MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

6666
Asthma
Treatment Phase: First-line prevention

**Population criteria:**
- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**
- The condition must be frequent intermittent; OR
- The condition must be mild persistent, AND
- The treatment must be the single preventer agent, AND
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**montelukast 4 mg chewable tablet, 28**

<table>
<thead>
<tr>
<th>8627C</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>.</td>
<td>18.24</td>
<td>19.45</td>
<td>APO-Montelukast [TX]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chemmart Montelukast [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Montelukast AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Montelukast Sandoz [SZ]</td>
</tr>
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<td>Terry White Chemists</td>
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<td>Montelukast [TW]</td>
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<td>3.00</td>
<td>21.24</td>
<td>19.45</td>
<td>Singulair [MK]</td>
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<td>Auro-Montelukast Tabs 4 [DO]</td>
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<td></td>
<td>Lukair [AL]</td>
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<td></td>
<td></td>
<td>Montelukast GH [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RespiKast 4 [RW]</td>
</tr>
</tbody>
</table>

**MONTELUKAST**

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

6674
Asthma
Treatment Phase: First-line prevention

**Clinical criteria:**
- The condition must be frequent intermittent; OR
- The condition must be mild persistent, AND
- The treatment must be the single preventer agent, AND
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**
- Patient must be aged 2 to 5 years inclusive.
**SENSE ORGANS**

**Authority required (STREAMLINED)**

**6684**

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**
- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; **OR**
- The treatment must be as an alternative to adding eformoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**
- Patient must be aged 6 to 14 years inclusive.

**montelukast 5 mg chewable tablet, 28**

<table>
<thead>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**Cough and Cold Preparations**

**COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS**

***Opium alkaloids and derivatives***

**CODEINE**

**codeine phosphate 30 mg tablet, 20**

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**ANTIHISTAMINES FOR SYSTEMIC USE**

***Phenothiazine derivatives***

**PROMETHAZINE**

**promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules**

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<thead>
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<td>1948M</td>
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</table>

**SENSORY ORGANS**

**OPHTHALMOLOGICALS**

**ANTIINFECTIVES**

***Antibiotics***

**AZITHROMYCIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Trachoma

**azithromycin 500 mg tablet, 2**

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</table>
## Sensory Organs

### Azithromycin

**200 mg/5 mL powder for oral liquid, 15 mL**

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### Chloramphenicol

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**0.5% eye drops, 10 mL**

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### Gentamicin

**Restricted benefit**

- Perioperative use in ophthalmic surgery
- Suspected Pseudomonal eye infection

**0.3% eye drops, 5 mL**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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### Gentamicin

**Restricted benefit**

- Invasive ocular infection
- Perioperative use in ophthalmic surgery
- Suspected Pseudomonal eye infection

**0.3% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>Genoptic [AG]</td>
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### Tobramycin

**Restricted benefit**

- Perioperative use in ophthalmic surgery
- Suspected Pseudomonal eye infection

**0.3% eye ointment, 3.5 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**0.3% eye drops, 5 mL**

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### Tobramycin

**Restricted benefit**

- Invasive ocular infection
- Perioperative use in ophthalmic surgery
- Suspected Pseudomonal eye infection

**0.3% eye ointment, 3.5 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**0.3% eye drops, 5 mL**

<table>
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### Antivirals
## Sensory Organs

### Aciclovir

**Restricted benefit**

Herpes simplex keratitis

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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### Fluoroquinolones

**Ciprofloxacin**

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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### Ofloxacin

**Authority required**

Bacterial keratitis

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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### Antiinflammatory Agents

**Corticosteroids, plain**
### Sensory Organs

#### Dexamethasone

**Dexamethasone Eye drops 1 mg per mL (0.1%), 5 mL, 1**

<table>
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<tr>
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</table>

**Note**
- No applications for increased maximum quantities will be authorised.
- No applications for increased repeats will be authorised.

#### Dexamethasone

**Dexamethasone Eye drops 1 mg per mL (0.1%), 5 mL, 1**

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<td>..</td>
<td>14.73</td>
<td>15.94 Maxidex [NV]</td>
</tr>
</tbody>
</table>

**Note**
- Special Pricing Arrangements apply.

---

**Authority required**

Diabetic macular oedema (DMO)
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to diabetic macular oedema, AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Authority approval for initial treatment of each eye must be sought.

A written application must include:
- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
- Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
- Applications for authority to prescribe should be forwarded to:
  - Department of Human Services
  - Complex Drugs
  - Reply Paid 9826
  - HOBART TAS 7001

**Note**
- The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

---

**Authority required**

Diabetic macular oedema (DMO)
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

---

General Pharmaceutical Benefits
SENSORY ORGANS

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Diabetic macular oedema (DMO)
Treatment Phase: Grandfathering treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Clinical criteria:**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2016, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

The first authority application for each eye must be made in writing or by telephone. A written application must include:
- a) a completed authority prescription form;
- b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

dexamethasone 700 microgram implant, 1

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**FLUOROMETHOLONE**

**fluorometholone 0.1% eye drops, 5 mL**

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**FLUOROMETHOLONE**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**fluorometholone 0.1% eye drops, 5 mL**

<table>
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<th>Max Qty</th>
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**FLUOROMETHOLONE ACETATE**

**fluorometholone acetate 0.1% eye drops, 5 mL**

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<td>Flarex [NV]</td>
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**FLUOROMETHOLONE ACETATE**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.
fluorometholone acetate 0.1% eye drops, 5 mL

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer

‡1  ..  ..  14.55  15.76  Flarex [NV]

HYDROCORTISONE ACETATE

hydrocortisone acetate 1% eye ointment, 5 g

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer

‡1  ..  ..  16.54  17.75  Hycor [QA]

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

Corticosteroids and mydriatics in combination

PREDNISOLONE ACETATE + PHENYLEPHRINE

Restricted benefit

Corneal grafts
Restricted benefit

Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer

‡1  2  ..  27.96  29.17  Prednefrin Forte [AG]

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

ANTIGLAUCOMA PREPARATIONS AND MIOTICS

Sympathomimetics in glaucoma therapy1)

APRACLONIDINE

Restricted benefit
Intra-ocular pressure
Clinical criteria:
- The treatment must be for short-term reduction of intra-ocular pressure, AND
- Patient must already be on maximally tolerated anti-glaucoma therapy.

apraclonidine 0.5% eye drops, 10 mL

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer

‡1  2  ..  40.40  38.80  Iopidine 0.5% [NV]

Note For prescribing in accordance with Optometry Board of Australia guidelines.

BRIMONIDINE

brimonidine tartrate 0.2% eye drops, 5 mL

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer

‡1  5  ..  23.02  24.23  * Enidin [PE]

*1.42  24.44  24.23  * Alphagan [AG]

brimonidine tartrate 0.15% eye drops, 5 mL

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer

‡1  5  ..  23.02  24.23  Alphagan P 1.5 [AG]

Note For prescribing in accordance with Optometry Board of Australia guidelines.
brimonidine tartrate 0.2% eye drops, 5 mL

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<td>Combigan [AG]</td>
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</table>

BRIMONIDINE + TIMOLOL

Restricted benefit

- Elevated intra-ocular pressure

Clinical criteria:
- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>Combigan P 1.5 [AG]</td>
</tr>
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</table>

BRIMONIDINE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

- Elevated intra-ocular pressure

Clinical criteria:
- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

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<td>18.70</td>
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</tr>
<tr>
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<td>21.18</td>
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PILOCARPINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

pilocarpine hydrochloride 1% eye drops, 15 mL

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<td>2598R</td>
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<td>21.18</td>
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<td>Isopto Carpine [NV]</td>
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</table>

Carboxy anhydrase inhibitors

Carbonic anhydrase inhibitors
### ACETAZOLAMIDE

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>acetazolamide 250 mg tablet, 100</th>
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<tr>
<td>1004W</td>
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### BRINZOLAMIDE

**brinzolamide 1% eye drops, 5 mL**

<table>
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<tr>
<th>brinzolamide 1% eye drops, 5 mL</th>
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<tbody>
<tr>
<td>8483L</td>
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<td>4.78</td>
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</tbody>
</table>

### BRINZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>brinzolamide 1% eye drops, 5 mL</th>
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<tbody>
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<td>Max Qty Packs</td>
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### BRINZOLAMIDE + BRIMONIDINE

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

<table>
<thead>
<tr>
<th>brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL</th>
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<tbody>
<tr>
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### BRINZOLAMIDE + BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL</th>
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<tbody>
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<tr>
<td>Max Qty Packs</td>
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<tr>
<td>‡1</td>
</tr>
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### BRINZOLAMIDE + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

<table>
<thead>
<tr>
<th>brinzolamide 1% + timolol 0.5% eye drops, 5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>3438Y</td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>‡1</td>
</tr>
</tbody>
</table>

### BRINZOLAMIDE + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
• The condition must have been inadequately controlled with monotherapy, AND
• Patient must have open-angle glaucoma; OR
• Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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**DORZOLAMIDE**

**dorzolamide 2% eye drops, 5 mL**

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<th>Max Qty Packs</th>
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<td>* Trusanide [OA] * Trusopt [MF]</td>
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</table>

**DORZOLAMIDE**

Note: For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>* Trusanide [OA] * Trusopt [MF]</td>
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</table>

**DORZOLAMIDE + TIMOLOL**

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:
• The condition must have been inadequately controlled with monotherapy, AND
• Patient must have open-angle glaucoma; OR
• Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<td>25.29</td>
<td>* Cosdor [QA] * DORZOLAMIDE/TIMOLOL AN 20/5 [EA]</td>
</tr>
</tbody>
</table>

* Dorzolamide/Timolol Sandoz 20/5 [SZ]

*1.00 25.08 25.29 * Cosopt [MF]

**DORZOLAMIDE + TIMOLOL**

Note: For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:
• The condition must have been inadequately controlled with monotherapy, AND
• Patient must have open-angle glaucoma; OR
• Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>25.29</td>
<td>* Cosdor [QA] * DORZOLAMIDE/TIMOLOL AN 20/5 [EA]</td>
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</tbody>
</table>

* Dorzolamide/Timolol Sandoz 20/5 [SZ]

*1.00 25.08 25.29 * Cosopt [MF]

**BETAXOLOL**

**betaxolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</table>

*4.76 23.11 19.56 * Betoptic [NV]

**betaxolol 0.25% eye drops, 5 mL**

<table>
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<tr>
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**BETAXOLOL**

Note: For prescribing in accordance with Optometry Board of Australia guidelines.
<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<th>MRVSN $</th>
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</thead>
<tbody>
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<td>betaxolol 0.5% eye drops, 5 mL</td>
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<td>18.35</td>
<td>19.56</td>
<td>19.56</td>
</tr>
<tr>
<td>betaxolol 0.25% eye drops, 5 mL</td>
<td>5</td>
<td>23.11</td>
<td>19.56</td>
<td>19.56</td>
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<tr>
<td>timolol 0.1% eye gel, 5 g</td>
<td>5</td>
<td>16.70</td>
<td>17.91</td>
<td>17.91</td>
</tr>
<tr>
<td>timolol 0.5% eye drops, 2.5 mL</td>
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<td>16.21</td>
<td>17.42</td>
<td>17.42</td>
</tr>
<tr>
<td>timolol 0.5% eye drops, 5 mL</td>
<td>5</td>
<td>15.54</td>
<td>16.75</td>
<td>16.75</td>
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<tr>
<td>timolol 0.1% eye gel, 5 g</td>
<td>5</td>
<td>16.70</td>
<td>17.91</td>
<td>17.91</td>
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<tr>
<td>timolol 0.5% eye drops, 2.5 mL</td>
<td>5</td>
<td>16.21</td>
<td>17.42</td>
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<tr>
<td>timolol 0.5% eye drops, 5 mL</td>
<td>5</td>
<td>15.54</td>
<td>16.75</td>
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<tr>
<td>timolol 0.5% eye drops, 2.5 mL</td>
<td>5</td>
<td>16.21</td>
<td>17.42</td>
<td>17.42</td>
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<tr>
<td>timolol 0.5% eye drops, 5 mL</td>
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<td>15.54</td>
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**Prostaglandin analogues1)**

<table>
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<tbody>
<tr>
<td>bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses</td>
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<td>32.01</td>
<td>33.22</td>
<td>33.22</td>
</tr>
<tr>
<td>bimatoprost 0.03% eye drops, 3 mL</td>
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<td>36.01</td>
<td>37.22</td>
<td>37.22</td>
</tr>
<tr>
<td>bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses</td>
<td>5</td>
<td>32.01</td>
<td>33.22</td>
<td>33.22</td>
</tr>
</tbody>
</table>
### SENSORY ORGANS

#### BIMATOPROST + TIMOLOL

**Restricted benefit**  
Elevated intra-ocular pressure  
Clinical criteria:  
- The condition must have been inadequately controlled with monotherapy, **AND**  
- Patient must have open-angle glaucoma; **OR**  
- Patient must have ocular hypertension.

**Bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>36.01</td>
<td>37.22</td>
<td>* Bimatoprost Sandoz [SZ] * Lumigan [AG]</td>
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**Bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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**Bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

<table>
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<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
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<td>40.46</td>
<td>38.80</td>
<td>GANfort 0.3/5 [AG]</td>
</tr>
</tbody>
</table>

**Bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>5</td>
<td>..</td>
<td>35.74</td>
<td>36.95</td>
<td>GANfort PF 0.3/5 [AG]</td>
</tr>
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**Bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

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<td>5</td>
<td>..</td>
<td>40.46</td>
<td>38.80</td>
<td>GANfort 0.3/5 [AG]</td>
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#### LATANOPROST

**Latanoprost 0.005% eye drops, 2.5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</table>

**Note**  
For prescribing in accordance with Optometry Board of Australia guidelines.

**Latanoprost 0.005% eye drops, 2.5 mL**

<table>
<thead>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Note**  
For prescribing in accordance with Optometry Board of Australia guidelines.
**LATANOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

**Ilatanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>21.37</td>
<td>22.58</td>
<td>* APO-Latanoprost/Timolol</td>
<td>* Lantim [JU]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.05/5 [TX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Latanoprost/timolol AN 50/5 [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>* Xalacom [PF]</td>
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<td>* Latanoprost/Timolol Sandoz 50/5 [SZ]</td>
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<td></td>
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<td>* Xalamol 50/5 [QA]</td>
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</table>

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**TAFLUPROST**

tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>34.92</td>
<td>36.13</td>
<td>Saflutan [MF]</td>
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</tbody>
</table>

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**TRAVOPROST**

travoprost 0.004% eye drops, 2.5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>40.75</td>
<td>38.80</td>
<td>Travatan [NV]</td>
</tr>
</tbody>
</table>

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.
SENSORY ORGANS

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

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<td>Duotrav [NV]</td>
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</table>

TRAVOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit
Elevated intra-ocular pressure
Clinical criteria:
- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

<table>
<thead>
<tr>
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<td>Duotrav [NV]</td>
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MYDRIATICS AND CYCLOPLEGICS

Anticholinergics

ATROPINE SULFATE

ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1

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DECONGESTANTS AND ANTIALLERGICS

Other antiallergics

CROMOGLYCATE

Restricted benefit
Vernal kerato-conjunctivitis

sodium cromoglycate 2% eye drops, 10 mL

<table>
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<tr>
<th>Max Qty Packs</th>
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sodium cromoglycate 2% eye drops, 10 mL

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpt</th>
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OCULAR VASCULAR DISORDER AGENTS

Antineovascularisation agents

AFLIBERCEPT

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Diabetic macular oedema (DMO)
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must have visual impairment due to diabetic macular oedema, AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
- Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
a) a completed authority prescription form;
b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

### Authority required
Diabetic macular oedema (DMO)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

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<td>Eylea [BN]</td>
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</table>

### Authority required
Subfoveal choroidal neovascularisation (CNV)

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:
- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
SENSORY ORGANS

Treatment Phase: Continuing treatment

Clinical criteria:
• The condition must be due to age-related macular degeneration (AMD), AND
• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:
• Must be treated by an ophthalmologist.

Note Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required
Branch retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), AND
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, AND
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
• Must be treated by an ophthalmologist.

Authority required
Branch retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
• Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required
Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
  a) a completed authority prescription form;
  b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
  c) a copy of the optical coherence tomography or fluorescein angiogram report.
A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
No increase in the maximum quantity or number of repeats may be authorised.

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### afibercept 4 mg/0.1 mL injection, 0.1 mL vial

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### RANIBIZUMAB

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

**Note**
Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Diabetic macular oedema (DMO)
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must have visual impairment due to diabetic macular oedema, **AND**
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, **AND**
• The treatment must be as monotherapy; OR
• The treatment must be in combination with laser photocoagulation, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
   a) a completed authority prescription form;
   b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
   c) a copy of the optical coherence tomography or fluorescein angiogram report.
   A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Prescribing information** (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

### Authority required

**Diabetic macular oedema (DMO)**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
   - Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
   - The treatment must be as monotherapy; **OR**
   - The treatment must be in combination with laser photocoagulation, **AND**
   - The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
   - Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<td>Lucentis [NV]</td>
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### Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

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### RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

**Subfoveal choroidal neovascularisation (CNV)**

**Treatment Phase:** Initial treatment

**Clinical criteria:**
   - The condition must be due to age-related macular degeneration (AMD), **AND**
   - The condition must be diagnosed by optical coherence tomography; **OR**
   - The condition must be diagnosed by fluorescein angiography, **AND**
   - The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
   - Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone. A written application must include:
   a) a completed authority prescription form;
   b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
   c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

*Note* Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Branch retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
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**Treatment criteria:**
- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone. A written application must include:
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*Note* No increase in the maximum number of repeats may be authorised.

**Authority required**
Branch retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

*Note* Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
• The condition must be diagnosed by optical coherence tomography; OR
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**Treatment criteria:**
• Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.

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**Note**
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**Note**
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**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.

**Note**
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**Note**
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**Note**
No increase in the maximum number of repeats may be authorised.

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

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<th>No. of Rpts</th>
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<th>MRSN $</th>
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<tr>
<td>1</td>
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<td>1149.44</td>
<td>38.80</td>
<td>* Lucentis [NV]</td>
<td></td>
</tr>
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</table>

**RANIBIZUMAB**

**Note**
Special Pricing Arrangements apply.

**Note**
Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

**Clinical criteria:**
• The condition must be due to age-related macular degeneration (AMD), AND
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:
- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Note**  Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Branch retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:
- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**  The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note**  Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**  No increase in the maximum quantity or number of units may be authorised.

**Note**  No increase in the maximum number of repeats may be authorised.

**Authority required**
Branch retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
• The condition must be diagnosed by optical coherence tomography; **OR**
• The condition must be diagnosed by fluorescein angiography, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
a) a completed authority prescription form;
b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.
A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
• Must be treated by an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

---

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**VERTEPORFIN**

**Note** The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

**Clinical criteria:**
• The condition must be predominantly classic (greater than or equal to 50%).
**SENSORY ORGANS**

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a baseline visual acuity equal to or better than 6/60 (20/200).

The first authority application for each eye must be made in writing or by telephone. A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note**
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note**
No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

**Note**
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
**Subfoveal choroidal neovascularisation (CNV)**
**Treatment Phase:** Initial PBS-subsidised treatment

**Clinical criteria:**
- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- Patient must have been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

The first authority application for each eye must be made in writing or by telephone. A written application must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form, which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note**
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note**
A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

**Note**
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
**Subfoveal choroidal neovascularisation (CNV)**
**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**
- Must be treated by an ophthalmologist.

**Note**
A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

**Note**
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
## SENSORY ORGANS

### verteporfin 15 mg injection, 1 vial

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### OTHER OPHTHALMOLOGICALS

#### CARBOMER-974

**Authority required (STREAMLINED)**

**6172**
Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

#### CARBOMER-974 0.3% eye gel, 30 x 500 mg unit doses

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#### CARBOMER-974 0.3% eye gel, 30 x 500 mg unit doses

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#### CARBOMER-980

**Restricted benefit**
Severe dry eye syndrome, including Sjogren’s syndrome

#### CARBOMER-980 0.2% eye gel, 10 g

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#### CARBOMER-980 0.2% eye drops, 30 x 0.6 mL unit doses

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#### CARBOMER-980 0.2% eye drops, 30 x 0.6 mL unit doses

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#### CARBOMER-980

**Authority required (STREAMLINED)**

**6172**
Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

#### CARBOMER-980 0.2% eye drops, 30 x 0.6 mL unit doses

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#### CARBOMER-980 0.2% eye drops, 30 x 0.6 mL unit doses

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<td>*36.88</td>
<td>38.09</td>
<td>Viscotears Gel PF [IV]</td>
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</table>

#### CARBOMER-980

**Restricted benefit**
Severe dry eye syndrome, including Sjogren’s syndrome

**Clinical criteria:**
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

#### CARBOMER-980 0.2% eye gel, 10 g

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#### CARMELLOSE SODIUM

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

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**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

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<th>Max Qty Packs</th>
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### CARMELLOSE SODIUM

**Restricted benefit**

Severe dry eye syndrome

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

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<tr>
<th>Max Qty Packs</th>
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**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

<table>
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<tr>
<th>Max Qty Packs</th>
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### CARMELLOSE SODIUM

**Authority required (STREAMLINED)**

6172

Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses**

<table>
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<tr>
<th>Max Qty Packs</th>
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**carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses**

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**carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

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**carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

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<td>32.84</td>
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**carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses**

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**carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses**

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**carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

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**carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*31.63</td>
<td>32.84</td>
<td>* Optifresh Plus [PP]</td>
</tr>
<tr>
<td>2324H</td>
<td>5</td>
<td>..</td>
<td>*31.63</td>
<td>32.84</td>
<td>* Celluvisc [AG]</td>
</tr>
</tbody>
</table>

### CARMELLOSE SODIUM

**Note** No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.

### Carboxymethylcellulose sodium 1% (10 mg/mL) eye drops, 15 mL

**carmellose sodium 1% (10 mg/mL) eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>9212W</td>
<td>1</td>
<td>14.54</td>
<td>15.75</td>
<td></td>
</tr>
</tbody>
</table>

**Brand Name and Manufacturer**

Refresh Liquigel [AG]

### Carboxymethylcellulose sodium 0.5% (5 mg/mL) eye drops, 15 mL

**carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>9211T</td>
<td>1</td>
<td>14.54</td>
<td>15.75</td>
<td></td>
</tr>
</tbody>
</table>

**Brand Name and Manufacturer**

Refresh Tears Plus [AG]

### Carboxymethylcellulose SODIUM + GLYCEROL

**Carboxymethylcellulose sodium 0.5% + glycerol 0.9% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>5556K</td>
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<td>14.54</td>
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</tr>
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</table>

**Brand Name and Manufacturer**

Optive [AG]

### Dextran-70 + Hypromellose

**Dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1509K</td>
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<td>14.63</td>
<td>15.84</td>
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</tr>
</tbody>
</table>

**Brand Name and Manufacturer**

Poly-Tears [NM]

Tears Naturale [NV]

### Authority required (STREAMLINED)
SENSORY ORGANS

Severe dry eye syndrome

Clinical criteria:
- Patient must be sensitive to preservatives in multi-dose eye drops.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5521N</td>
<td>3</td>
<td>5</td>
<td>*35.98</td>
<td>37.19</td>
<td>Bion Tears [NV]</td>
</tr>
</tbody>
</table>

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8299T</td>
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<td>5</td>
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<td>37.19</td>
<td>Bion Tears [NV]</td>
</tr>
</tbody>
</table>

**DEXTRAN-70 + HYPROMELLOSE**

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

Clinical criteria:
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>9216C</td>
<td>‡1</td>
<td>11</td>
<td>14.63</td>
<td>15.84</td>
<td>* Poly-Tears [NM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.65</td>
<td>18.28</td>
<td>* Tears Naturale [NV]</td>
</tr>
</tbody>
</table>

**HYPROMELLOSE**

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>8287E</td>
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<td>15.65</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.00</td>
<td>18.44</td>
<td>* Genteal [NV]</td>
</tr>
</tbody>
</table>

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>5</td>
<td>14.44</td>
<td>15.65</td>
<td>Methopt [QA]</td>
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</table>

**HYPROMELLOSE**

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

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<tr>
<th>Max Qty Packs</th>
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<td>* In a Wink Moisturising [NM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.00</td>
<td>18.44</td>
<td>* Genteal [NV]</td>
</tr>
</tbody>
</table>

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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</thead>
<tbody>
<tr>
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<td>‡1</td>
<td>5</td>
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<td>15.65</td>
<td>Methopt [QA]</td>
</tr>
</tbody>
</table>

**HYPROMELLOSE**

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

Clinical criteria:
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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</tr>
<tr>
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<td>4.00</td>
<td>18.44</td>
<td>* Genteal [NV]</td>
</tr>
</tbody>
</table>
### SENSORY ORGANS

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>15.65</td>
<td>Methopt [QA]</td>
</tr>
</tbody>
</table>

**HYDROXYPROPYL METHYLCELLULOSE**

**HYDROXYPROPYL METHYLCELLULOSE + CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

**Hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>15.65</td>
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<td>15.65</td>
<td></td>
<td>Genteal gel [NV]</td>
</tr>
</tbody>
</table>

**HYDROXYPROPYL METHYLCELLULOSE + CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

**Hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>14.44</td>
<td>15.65</td>
<td>* HPMC PAA [NM]</td>
</tr>
<tr>
<td>^4,00</td>
<td></td>
<td>18.44</td>
<td>15.65</td>
<td></td>
<td>Genteal gel [NV]</td>
</tr>
</tbody>
</table>

**HYDROXYPROPYL METHYLCELLULOSE + CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

**Clinical criteria:**

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>15.65</td>
<td>* HPMC PAA [NM]</td>
</tr>
<tr>
<td>^4,00</td>
<td></td>
<td>18.44</td>
<td>15.65</td>
<td></td>
<td>Genteal gel [NV]</td>
</tr>
</tbody>
</table>

**OCRIPLASMIN**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Vitreomacular traction syndrome

**Clinical criteria:**

- Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR
- Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography, AND
- The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, AND
- Patient must not have an epiretinal membrane attached to the vitreomacular traction, AND
- The condition must be previously untreated in the eye proposed for treatment, AND
- Patient must not have received prior vitrectomy in the eye proposed for treatment, AND
- Patient must be symptomatic.

**Treatment criteria:**

- Must be treated by an ophthalmologist. The prescriber must state which eye(s) is being treated at the time of application.

**Ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>
PARAFFIN

paraffin 1 g/g eye ointment, 2 x 3.5 g

1750D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
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<td>23.42</td>
<td>24.63</td>
<td>Poly Visc [NV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.84</td>
<td>25.26</td>
<td>Ircal [PE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td></td>
<td>Refresh Night Time [AG]</td>
</tr>
</tbody>
</table>

paraffin 1 g/g eye ointment, 2 x 3.5 g

5522P

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
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<td>..</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td></td>
<td>Refresh Night Time [AG]</td>
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paraffin 1 g/g eye ointment, 3.5 g

1754H

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>*23.97</td>
<td>25.18</td>
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<td>Poly Visc [NV]</td>
</tr>
</tbody>
</table>

paraffin 1 g/g eye ointment, 3.5 g

5523Q

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>*23.97</td>
<td>25.18</td>
<td></td>
<td>Poly Visc [NV]</td>
</tr>
</tbody>
</table>

PARAFFIN

Note: No increase in the maximum number of repeats may be authorised.

Note: No increase in the maximum number of units may be authorised.

Restricted benefit
For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 2 x 3.5 g

9218E

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
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<td>11</td>
<td>..</td>
<td>23.42</td>
<td>24.63</td>
<td>Poly Visc [NV]</td>
</tr>
<tr>
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<td></td>
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<td>1.84</td>
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<td>Ircal [PE]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>*</td>
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<td>Refresh Night Time [AG]</td>
</tr>
</tbody>
</table>

PARAFFIN

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Restricted benefit
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paraffin 1 g/g eye ointment, 3.5 g

9217D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>11</td>
<td>*23.97</td>
<td>25.18</td>
<td></td>
<td>Poly Visc [NV]</td>
</tr>
</tbody>
</table>

PARAFFIN

Note: The in-use shelf life of VitA-POS is 6 months from the date of opening.

paraffin + retinol palmitate 0.0138% eye ointment, 5 g

2167C

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<tbody>
<tr>
<td>2</td>
<td>5</td>
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<td>VitA-POS [AE]</td>
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paraffin + retinol palmitate 0.0138% eye ointment, 5 g

2222Y

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>5</td>
<td>*23.97</td>
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<td></td>
<td>VitA-POS [AE]</td>
</tr>
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PARAFFIN

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Restricted benefit
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paraffin + retinol palmitate 0.0138% eye ointment, 5 g

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<td>11</td>
<td>..</td>
<td>*23.97</td>
<td>25.18</td>
<td>VitA-POS [AE]</td>
</tr>
</tbody>
</table>

### POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**
Severe dry eye syndrome, including Sjogren’s syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1†</td>
<td>5</td>
<td>..</td>
<td>14.54</td>
<td>15.75</td>
<td>Systane [NV]</td>
</tr>
</tbody>
</table>

### POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**
Severe dry eye syndrome, including Sjogren’s syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>1†</td>
<td>5</td>
<td>..</td>
<td>14.54</td>
<td>15.75</td>
<td>Systane [NV]</td>
</tr>
</tbody>
</table>

### POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Authority required (STREAMLINED)**

**6172**
Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2†</td>
<td>5</td>
<td>..</td>
<td>*33.95</td>
<td>35.16</td>
<td>Systane [NV]</td>
</tr>
</tbody>
</table>

### POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
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<td>5</td>
<td>..</td>
<td>*33.95</td>
<td>35.16</td>
<td>Systane [NV]</td>
</tr>
</tbody>
</table>

### POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*33.95</td>
<td>35.16</td>
<td>Systane [NV]</td>
</tr>
</tbody>
</table>

### POLYVINYL ALCOHOL

**Restricted benefit**
Severe dry eye syndrome, including Sjogren’s syndrome

**polyvinyl alcohol 1.4% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1†</td>
<td>5</td>
<td>..</td>
<td>14.44</td>
<td>15.65</td>
<td>PVA Tears [PE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.39</td>
<td>15.83</td>
<td>Liquifilm Tears [AG]</td>
</tr>
</tbody>
</table>

**polyvinyl alcohol 1.4% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1†</td>
<td>5</td>
<td>..</td>
<td>14.44</td>
<td>15.65</td>
<td>Vistil [AE]</td>
</tr>
</tbody>
</table>

**polyvinyl alcohol 3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1†</td>
<td>5</td>
<td>..</td>
<td>14.44</td>
<td>15.65</td>
<td>Vistil Forte [AE]</td>
</tr>
</tbody>
</table>
### POLYVINYL ALCOHOL

**Restricted benefit**
Severe dry eye syndrome, including Sjogren’s syndrome

**polyvinyl alcohol 1.4% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Max Qty Packs</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVA Tears PE</td>
<td>PVA Tears</td>
<td>‡1 5</td>
<td>14.44</td>
<td>15.65</td>
<td>*</td>
</tr>
<tr>
<td>Liquifilm AG</td>
<td>Liquifilm</td>
<td>‡1.39 5</td>
<td>15.83</td>
<td>15.65</td>
<td>*</td>
</tr>
</tbody>
</table>

**polyvinyl alcohol 1.4% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
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<th>Premium ($)</th>
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<tbody>
<tr>
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<td>Vistil</td>
<td>‡1 5</td>
<td>14.44</td>
<td>15.65</td>
<td>*</td>
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</tbody>
</table>

**polyvinyl alcohol 3% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Max Qty Packs</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Vistil Forte [AE]</td>
<td>Vistil Forte</td>
<td>‡1 5</td>
<td>14.44</td>
<td>15.65</td>
<td>*</td>
</tr>
</tbody>
</table>

### POLYVINYL ALCOHOL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Clinical criteria:**
- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**polyvinyl alcohol 1.4% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Max Qty Packs</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVA Tears PE</td>
<td>PVA Tears</td>
<td>‡1 11</td>
<td>14.44</td>
<td>15.65</td>
<td>*</td>
</tr>
<tr>
<td>Liquifilm AG</td>
<td>Liquifilm</td>
<td>‡1.39 11</td>
<td>15.83</td>
<td>15.65</td>
<td>*</td>
</tr>
</tbody>
</table>

**polyvinyl alcohol 1.4% eye drops, 15 mL**

<table>
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<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
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<td>15.65</td>
<td>*</td>
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</tbody>
</table>

**polyvinyl alcohol 3% eye drops, 15 mL**

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<tr>
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<td>Vistil Forte</td>
<td>‡1 11</td>
<td>14.44</td>
<td>15.65</td>
<td>*</td>
</tr>
</tbody>
</table>

### SODIUM HYALURONATE

**Note** The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

**Authority required (STREAMLINED)**

**Severe dry eye syndrome**

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Max Qty Packs</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hylo-Forte AE</td>
<td>Hylo-Forte</td>
<td>‡1 5</td>
<td>34.74</td>
<td>35.95</td>
<td>*</td>
</tr>
</tbody>
</table>

**sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Max Qty Packs</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
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<tbody>
<tr>
<td>Hylo-Forte AE</td>
<td>Hylo-Forte</td>
<td>‡1 5</td>
<td>34.74</td>
<td>35.95</td>
<td>*</td>
</tr>
</tbody>
</table>

**sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand Name</th>
<th>Max Qty Packs</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hylo-Fresh AE</td>
<td>Hylo-Fresh</td>
<td>‡1 5</td>
<td>34.74</td>
<td>35.95</td>
<td>*</td>
</tr>
</tbody>
</table>

**SOY LECITHIN + TOCOPHEROL + VITAMIN A**

**Authority required (STREAMLINED)**

**Severe dry eye syndrome**
SENSORY ORGANS

Severe dry eye syndrome

Clinical criteria:
• Patient must be sensitive to preservatives in multi-dose eye drops.

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>5545W</td>
<td>2</td>
<td>5</td>
<td>*35.59</td>
<td>36.80</td>
<td></td>
<td>tearsagain [RB]</td>
</tr>
</tbody>
</table>

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9448G</td>
<td>2</td>
<td>5</td>
<td>*35.59</td>
<td>36.80</td>
<td></td>
<td>tearsagain [RB]</td>
</tr>
</tbody>
</table>

OTOLOGICALS

ANTIINFECTIVES

CIPROFLOXACIN

Authority required
Chronic suppurative otitis media

Population criteria:
• Patient must be an Aboriginal or a Torres Strait Islander person, AND
• Patient must be aged 1 month or older.

Authority required
Chronic suppurative otitis media

Population criteria:
• Patient must be less than 18 years of age.

Clinical criteria:
• Patient must have perforation of the tympanic membrane.

Authority required
Chronic suppurative otitis media

Population criteria:
• Patient must be less than 18 years of age.

Clinical criteria:
• Patient must have a grommet in situ.

ciprofloxacin 0.3% ear drops, 5 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>2480M</td>
<td>†1</td>
<td>1</td>
<td></td>
<td>22.27</td>
<td>23.48</td>
<td>Citoxan [NV]</td>
</tr>
</tbody>
</table>

CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

Corticosteroids and antiinfectives in combination

FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE
framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>2781J</td>
<td>†1</td>
<td>2</td>
<td>14.15</td>
<td>15.36</td>
<td></td>
<td>Otodex [AV]</td>
</tr>
</tbody>
</table>

TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN
triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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<tbody>
<tr>
<td>2971J</td>
<td>†1</td>
<td>2</td>
<td>15.15</td>
<td>16.36</td>
<td></td>
<td>Otocomb Otic [FM]</td>
</tr>
</tbody>
</table>

triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
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<tbody>
<tr>
<td>2974M</td>
<td>†1</td>
<td>2</td>
<td>12.62</td>
<td>13.83</td>
<td></td>
<td>Otocomb Otic [FM]</td>
</tr>
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</table>

OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

ANTIINFECTIVES

Antiinfectives
### FRAMYCETIN SULFATE
framycetin sulfate 0.5% eye/ear drops, 8 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1440T</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>14.67</td>
<td>15.88 Soframycin [SW]</td>
</tr>
</tbody>
</table>

### HONEY BEE VENOM
bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2886X</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>264.51</td>
<td>38.80 Albey Bee Venom [DE]</td>
</tr>
</tbody>
</table>

**Note** Paper wasp venom is not European wasp venom

### PAPER WASP VENOM
Paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2918N</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>264.51</td>
<td>38.80 Albey Paper Wasp Venom [DE]</td>
</tr>
</tbody>
</table>

### VESPULA SPP VENOM
vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>2883R</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>264.51</td>
<td>38.80 Albey Yellow Jacket Venom [DE]</td>
</tr>
</tbody>
</table>

### ALL OTHER THERAPEUTIC PRODUCTS

#### Antidotes

### NALOXONE
naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10783M</td>
<td>1</td>
<td>..</td>
<td>82.48</td>
<td>38.80</td>
<td>* Naloxone Hydrochloride (DBL) * Naloxone Juno [JU] [PF]</td>
</tr>
</tbody>
</table>

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>10787R</td>
<td>1</td>
<td>..</td>
<td>82.48</td>
<td>38.80</td>
<td>* Naloxone Hydrochloride (DBL) * Naloxone Juno [JU] [PF]</td>
</tr>
</tbody>
</table>

naloxone hydrochloride 1 mg/ mL injection, 1 x 2 mL syringe

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>11077B</td>
<td>1</td>
<td>..</td>
<td>74.05</td>
<td>38.80</td>
<td>Prenoxad [PL]</td>
</tr>
</tbody>
</table>
**LANTHANUM**

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
5491
Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>281.53</td>
<td>38.80</td>
<td></td>
<td>Fosrenol [ZI]</td>
</tr>
</tbody>
</table>

**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>475.25</td>
<td>38.80</td>
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<td>Fosrenol [ZI]</td>
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**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

<table>
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<tr>
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**SEVELAMER**

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
5491
Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

**SEVELAMER hydrochloride 800 mg tablet, 180**

<table>
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<td>Renagel [GZ]</td>
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**SUCROFERRIC OXYHYDROXIDE**

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**
5491
Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation
Clinical criteria:
- The condition must not be adequately controlled by calcium, AND
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:
- Patient must be undergoing dialysis for chronic kidney disease.

iron (as sucralfate 200 mg tablet): chewable, 90

iron (as sucralfate 500 mg tablet): chewable, 90

Detoxifying agents for antineoplastic treatment

- **FOLINIC ACID**

  folinic acid 300 mg/30 mL injection, 30 mL vial

  folinic acid 1 g/100 mL injection, 100 mL vial

  folinic acid 50 mg/5 mL injection, 5 mL vial

  folinic acid 15 mg tablet, 10

  folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

  folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules

- **MESNA**

  Restricted benefit

  Urothelial toxicity

  Treatment Phase: Prophylaxis or reduction of toxicity

  Clinical criteria:
• The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

**mesna 1 g/10 mL injection, 15 x 10 mL ampoules**

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<tr>
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**mesna 400 mg/4 mL injection, 15 x 4 mL ampoules**

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<td>8078E</td>
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<td>94.74</td>
<td>38.80 Uromitexan [BX]</td>
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**Drugs for treatment of hypercalcemia**

- **PHOSPHORUS**
  - Authority required (STREAMLINED)
    - 5089 Hypophosphataemic rickets
    - Authority required (STREAMLINED)
    - 5114 Vitamin D-resistant rickets
    - Authority required (STREAMLINED)
    - 5095 Familial hypophosphataemia
    - Authority required (STREAMLINED)
    - 5123 Hypercalcaemia

  **phosphorus 500 mg effervescent tablet, 100**

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<td>76.04</td>
<td>38.80 Phosphate Sandoz [PL]</td>
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</table>

**Other therapeutic products**

- **POLYLACTIC ACID**
  
  **Note** No increase in the maximum quantity or number of units may be authorised.
  
  **Note** No increase in the maximum number of repeats may be authorised.
  
  **Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

  - Authority required
    - Severe facial lipoatrophy
    - Treatment Phase: Initial PBS-subsidised treatment
    - Clinical criteria:
      - The treatment must be for facial administration only, **AND**
      - The condition must be caused by therapy for HIV infection.
    - Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

  **polyactic acid 150 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>9475Q</td>
<td>2</td>
<td>4</td>
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<td>*419.77</td>
<td>38.80 Sculptra [GA]</td>
</tr>
</tbody>
</table>

- **POLYLACTIC ACID**
  
  **Note** No increase in the maximum quantity or number of units may be authorised.
  
  **Note** No increase in the maximum number of repeats may be authorised.
  
  **Note** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.
  
  **Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

  - Authority required
    - Severe facial lipoatrophy
    - Treatment Phase: Maintenance PBS-subsidised treatment
    - Clinical criteria:
      - The treatment must be for facial administration only, **AND**
      - The condition must be caused by therapy for HIV infection.
    - Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

  **polyactic acid 150 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>9476R</td>
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<td>..</td>
<td>*419.77</td>
<td>38.80 Sculptra [GA]</td>
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### Diagnostic Agents

#### Urine Tests

**Glucose and Ketone Indicator Urine**

*Restricted benefit*

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

<table>
<thead>
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<th>glucose and ketone indicator urine diagnostic strip, 50</th>
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<tbody>
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<tr>
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**Glucose Indicator Urine**

*Restricted benefit*

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

<table>
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<td>---------------</td>
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<tr>
<td>3104J</td>
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### General Nutrients

#### Other Nutrients

**Medium Chain Triglycerides**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6147

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Authority required (STREAMLINED)

6191

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

<table>
<thead>
<tr>
<th>triglycerides medium chain oral liquid, 18 x 250 mL cartons</th>
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</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>---------------</td>
</tr>
<tr>
<td>10049X</td>
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</table>

**Medium Chain Triglycerides**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6181

Chylous ascites

Authority required (STREAMLINED)

6134

Chylothorax

Authority required (STREAMLINED)

6164

Fat malabsorption

Clinical criteria:

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.
Authority required (STREAMLINED)
6203
Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)
6155
Intractable childhood epilepsy

Clinical criteria:
• Patient must require a ketogenic diet.

Authority required (STREAMLINED)
6135
Cerebrospinal fluid glucose transporter defect

Clinical criteria:
• Patient must require a ketogenic diet.

Authority required (STREAMLINED)
6146
Long chain fatty acid oxidation disorders

medium chain triglycerides oral oil, 500 mL

<table>
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<td>*50.49</td>
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<td>MCT Oil [SB]</td>
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medium chain triglycerides oral liquid, 250 mL bottle

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<td>*191.63</td>
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<td>Liquigen [SB]</td>
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**PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS**

Note: No increase in the maximum number of repeats may be authorised.

Note: Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit
Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:
• Patient must have fat malabsorption due to liver disease; OR
• Patient must have fat malabsorption due to short gut syndrome; OR
• Patient must have fat malabsorption due to cystic fibrosis; OR
• Patient must have fat malabsorption due to gastrointestinal disorders.

Population criteria:
• Patient must be aged from 1 to 10 years inclusive.

protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 8 x 500 mL pouches

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<td>Nutrini Peptisorb Energy [NU]</td>
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**TRIGLYCERIDES LONG CHAIN**

Note: Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

Restricted benefit
Ketogenic diet

Clinical criteria:
• Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
• Patient must have a glucose transport protein defect; OR
• Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

triglycerides long chain oral liquid, 18 x 250 mL cartons

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<td>*289.83</td>
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<td>38.80</td>
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</table>

**AMINO ACID SYNTHETIC FORMULA**

Note: Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required
Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:
• Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**
• Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**
Eosinophilic oesophagitis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
• Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**
• Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

### AMINO ACID SYNTHETIC FORMULA

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

#### amino acid synthetic formula powder for oral liquid, 400 g

<table>
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<tr>
<th>Max Qty</th>
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<th>No. of Rpts</th>
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<td>Neocate Advance Vanilla [SB]</td>
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#### amino acid synthetic formula powder for oral liquid, 400 g

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<td>EleCare [AB]</td>
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**AMINO ACID SYNTHETIC FORMULA**

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**

**Cows' milk protein enteropathy**

**Treatment Phase:** Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux, AND
• Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
• Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Severe cows’ milk protein enteropathy with failure to thrive**

**Treatment Phase:** Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae**

**Treatment Phase:** Initial treatment for up to 6 months
Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:
- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### AMINO ACID SYNTHETIC FORMULA

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### Authority required
Cows’ milk anaphylaxis

**Treatment criteria:**
- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
Cows’ milk protein enteropathy

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux. **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
Severe cows’ milk protein enteropathy with failure to thrive

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux. **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:
• The condition must not be isolated infant colic or reflux.

Population criteria:
• Patient must be older than 24 months of age.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:
• Patient must have failed to respond to protein hydrolysate formulae; OR
• Patient must have been receiving parenteral nutrition.

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows’ milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
• The condition must not be isolated infant colic or reflux, AND
• Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be up to the age of 24 months.
  The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be up to the age of 24 months.
  The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
• Patient must be up to the age of 24 months.
  The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows’ milk anaphylaxis

**Treatment criteria:**
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
• Patient must be up to the age of 24 months.
  Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
  The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows’ milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux. **AND**
  • Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
• Patient must be up to the age of 24 months.
  The name of the specialist and the date of birth of the patient must be included in the authority application.

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note**
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

Cows’ milk anaphylaxis

**Treatment criteria:**
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
• Patient must be up to the age of 24 months.
  Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
  The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows’ milk protein enteropathy

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux. **AND**
  • Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
• Patient must be up to the age of 24 months.
  The name of the specialist and the date of birth of the patient must be included in the authority application.
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:
• The condition must not be isolated infant colic or reflux, AND
• Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:
• The condition must not be isolated infant colic or reflux.

Population criteria:
• Patient must be older than 24 months of age.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:
• Patient must have failed to respond to protein hydrolysate formulae; OR
• Patient must have been receiving parenteral nutrition.

Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:
• Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:
• Patient must be 18 years of age or less.
Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

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### AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

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### Authority required

Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:
• Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:
• Patient must be 18 years of age or less.
Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**
- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

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**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

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**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.

**Authority required**

Cows’ milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows’ milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months
Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**
Cows’ milk anaphylaxis
Treatment criteria:
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.
Population criteria:
• Patient must be up to the age of 24 months.
Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk protein enteropathy
Treatment Phase: Continuing treatment
Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
Clinical criteria:
• The condition must not be isolated infant colic or reflux, **AND**
• Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment
Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.
Clinical criteria:
• The condition must not be isolated infant colic or reflux, **AND**
• Patient must have had failure to thrive prior to commencement with initial treatment.
Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment
Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.
Clinical criteria:
• The condition must not be isolated infant colic or reflux.
Population criteria:
• Patient must be older than 24 months of age.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority required**
Cows’ milk protein enteropathy
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk anaphylaxis
Treatment criteria:
- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
• Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
• Patient must have failed to respond to protein hydrolysate formulae; OR
• Patient must have been receiving parenteral nutrition.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
• Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**
• Patient must be 18 years of age or less.
Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Cows’ milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux. **AND**
• Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be older than 24 months of age.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
• Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**
• Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

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**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
Cows’ milk protein enteropathy and intolerance to soy protein
Treatment Phase: Initial treatment

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.
Clinical criteria:
- The condition must not be isolated infant colic or reflux, AND
- Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.
Population criteria:
- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

### 6193
Cows’ milk protein enteropathy and intolerance to soy protein

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, AND
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

### 6204
Cows’ milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, AND
- Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

**Population criteria:**
- Patient must be older than 24 months of age.
- The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

### 6137
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

**Treatment Phase:** Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

### 6182
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

### 6194
Biliary atresia

**Authority required (STREAMLINED)**

### 6157
Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

### 6205
Chylous ascites

**Authority required (STREAMLINED)**

### 6195
Cystic fibrosis

**Authority required (STREAMLINED)**

### 6158
Enterokinase deficiency

**Authority required (STREAMLINED)**
**Proven fat malabsorption**

**Authority required (STREAMLINED)**

**Severe diarrhoea of greater than 2 weeks duration**

**Population criteria:**
- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

**Severe intestinal malabsorption including short bowel syndrome**

**Protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g**

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**Protein Hydrolysate Formula with Medium Chain Triglycerides**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**6174**

**Cows’ milk protein enteropathy and intolerance to soy protein**

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux. **AND**
- Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

**6193**

**Cows’ milk protein enteropathy and intolerance to soy protein**

**Treatment Phase: Continuing treatment**

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux. **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Authority required (STREAMLINED)**

**6204**

**Cows’ milk protein enteropathy and intolerance to soy protein**

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux. **AND**
- Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

**Population criteria:**
- Patient must be older than 24 months of age.
- The name of the specialist must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**6137**

**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**

**Treatment Phase: Initial treatment for up to 6 months**

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**
- Patient must be up to the age of 24 months.
The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

**6182**
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

**6194**
Biliary atresia

**Authority required (STREAMLINED)**

**6157**
Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

**6205**
Chyloous ascites

**Authority required (STREAMLINED)**

**6195**
Cystic fibrosis

**Authority required (STREAMLINED)**

**6158**
Enterokinase deficiency

**Authority required (STREAMLINED)**

**6166**
Proven fat malabsorption

**Authority required (STREAMLINED)**

**6148**
Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**
- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

**6138**
Severe intestinal malabsorption including short bowel syndrome

**Authority required (STREAMLINED)**

**6206**
Chylothorax

**Protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g**

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**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**
Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Triglycerides medium chain formula powder for oral liquid, 400 g**

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**Triglycerides medium chain formula powder for oral liquid, 400 g**

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### Triglycerides Medium Chain Formula

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

#### Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

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### Carbohydrates

#### Modified Long Chain Amylopectin

**Restricted benefit**

Glycogen storage disease

**modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets**

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#### Amino Acid Formula with Fat, Carbohydrate, Vitamins, Minerals, Trace Elements and Medium Chain Triglycerides

**Authority required**

Cows’ milk protein enteropathy

**Treatment Phase:** Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
• Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
• Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
• Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
• Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**
• Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.
Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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### Authority required
**Cows’ milk protein enteropathy**
**Treatment Phase:** Continuing treatment
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
**Severe cows’ milk protein enteropathy with failure to thrive**
**Treatment Phase:** Continuing treatment
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
**Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae**
**Treatment Phase:** Continuing treatment
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**
**Treatment Phase:** Continuing treatment
**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
**Cows’ milk anaphylaxis**
**Treatment criteria:**
- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
- Patient must be up to the age of 24 months.
- Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

**Authority required**
Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**
- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Cows’ milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

**Eosinophilic oesophagitis**

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**
- Patient must be 18 years of age or less.
- Treatment with oral steroids should not be commenced during the period of initial treatment.
- Eosinophilic oesophagitis is demonstrated by the following criteria:
  1. Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
  2. A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
  3. Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

<p>| amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides for oral liquid, 400 g |</p>
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### Authority required

**Cows’ milk protein enteropathy**

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required

**Severe cows’ milk protein enteropathy with failure to thrive**

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux, AND

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**
• The condition must not be isolated infant colic or reflux.

**Population criteria:**
• Patient must have had failure to thrive prior to commencement with initial treatment.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
• Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
• Patient must be up to the age of 24 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk anaphylaxis

**Treatment criteria:**
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
• Patient must be up to the age of 24 months.
Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
• Patient must have failed to respond to protein hydrolysate formulae; OR
• Patient must have been receiving parenteral nutrition.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**
• Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**
• Patient must be 18 years of age or less.
Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

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**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

**Milk substitutes**

**MILK POWDER LACTOSE FREE FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Chronic lactose intolerance

**Population criteria:**

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General Pharmaceutical Benefits 729
• Patient must be up to the age of 12 months.

Clinical criteria:
• The condition must be proven to be lactose intolerance.
Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.

## MILK POWDER LACTOSE FREE FORMULA

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: No more than 1 application per patient will be authorised.

### Authority required

Acute lactose intolerance

### Population criteria:

• Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

## MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.

### Authority required

Chronic lactose intolerance

### Population criteria:

• Patient must be up to the age of 12 months.

The condition must be proven to be lactose intolerance.

Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.

## MILK POWDER SYNTHETIC LOW CALCIUM

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Hypercalcaemia

Population criteria:
- Patient must be under the age of 4 years.

milk powder synthetic low calcium powder for oral liquid, 400 g

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Other combinations of nutrients

**AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 20 g sachets

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**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10683G</td>
<td>7</td>
<td>5</td>
<td>..</td>
<td>*1929.63</td>
<td>PKU Easy Microtabs [OH]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid oral liquid, 20 x 500 mL bottles

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10822N</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*633.75</td>
<td>PKU Baby [OH]</td>
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</table>

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3417W</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2393.07</td>
<td>HCU Anamix junior LQ [SB]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10632N</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*1905.85</td>
<td>PKU Easy Shake &amp; Go [OH]</td>
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</tbody>
</table>

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE**

**Restricted benefit**

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine oral liquid: powder for, 30 x 34 g bottles

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10934L</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2953.95</td>
<td>TYR Easy Shake &amp; Go [OH]</td>
</tr>
</tbody>
</table>
- **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

  **Restricted benefit**
  Tyrosinaemia

  amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

<table>
<thead>
<tr>
<th>9330C</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td></td>
<td>*2393.07</td>
<td>38.80</td>
<td>TYR Anamix junior LQ [SB]</td>
</tr>
</tbody>
</table>

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

  **Restricted benefit**
  Proven glutaric aciduria type 1

  amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets

<table>
<thead>
<tr>
<th>10715Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8</td>
<td>5</td>
<td></td>
<td>*2012.19</td>
<td>38.80</td>
<td>GA1 Anamix Junior [NU]</td>
</tr>
</tbody>
</table>

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

  **Restricted benefit**
  Proven glutaric aciduria type 1

  amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets

<table>
<thead>
<tr>
<th>9438R</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td></td>
<td>*2012.23</td>
<td>38.80</td>
<td>GA gel [VF]</td>
</tr>
</tbody>
</table>

  amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g

<table>
<thead>
<tr>
<th>10466W</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9</td>
<td>5</td>
<td></td>
<td>*2935.75</td>
<td>38.80</td>
<td>XLYS, LOW TRY Maxamum [SB]</td>
</tr>
</tbody>
</table>

  amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g

<table>
<thead>
<tr>
<th>2650L</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8</td>
<td>5</td>
<td></td>
<td>*2662.03</td>
<td>38.80</td>
<td>GA1 Anamix infant [SB]</td>
</tr>
</tbody>
</table>

  amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 25 g sachets

<table>
<thead>
<tr>
<th>5484P</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td></td>
<td>*3007.19</td>
<td>38.80</td>
<td>GA express 15 [VF]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

**Restricted benefit**
Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 24 g sachets

<table>
<thead>
<tr>
<th>8677Q</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td></td>
<td>*2012.23</td>
<td>38.80</td>
<td>HCU gel [VF]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 500 g

<table>
<thead>
<tr>
<th>8416Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8</td>
<td>5</td>
<td></td>
<td>*2579.95</td>
<td>38.80</td>
<td>XMET Maxamum [SB]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE** Oral liquid 125 mL, 30, 1

<table>
<thead>
<tr>
<th>1548L</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>5</td>
<td></td>
<td>*2953.90</td>
<td>38.80</td>
<td>HCU Lophlex LQ 20 [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets

<table>
<thead>
<tr>
<th>2639X</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td></td>
<td>*2012.23</td>
<td>38.80</td>
<td>HCU cooler 10 [VF]</td>
</tr>
</tbody>
</table>
**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

**Population criteria:**
- Patient must be an infant or a very young child.

amino acid formula with vitamins and minerals without methionine oral liquid: powder for oral liquid, 400 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8417B</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*726.03</td>
<td>38.80</td>
<td>HCU Anamix infant [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9133Q</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2953.95</td>
<td>38.80</td>
<td>HCU cooler 15 [VF]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8744F</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2953.95</td>
<td>38.80</td>
<td>HCU express 15 [VF]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**

**Restricted benefit**

Methylmalonic acidemia

**Restricted benefit**

Propionic acidemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 500 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8061G</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*2579.95</td>
<td>38.80</td>
<td>XMTVI Maxamum [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 24 g sachets

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3444G</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2012.23</td>
<td>38.80</td>
<td>MMA/PA gel [VF]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3443F</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2953.95</td>
<td>38.80</td>
<td>MMA/PA express 15 [VF]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1923F</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2953.95</td>
<td>38.80</td>
<td>MMA/PA cooler 15 [VF]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8058D</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*726.03</td>
<td>38.80</td>
<td>MMA/PA Anamix infant [SB]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**

**Restricted benefit**
### Methylmalonic acidaemia

**Restricted benefit**

**Propionic acidaemia**

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 18 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*2012.19</td>
<td>38.80</td>
<td>MMA/PA Anamix Junior [NU]</td>
</tr>
</tbody>
</table>

### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

#### Phenylketonuria

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*1930.63</td>
<td>38.80</td>
<td>PKUflex LQ 20 [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*1466.15</td>
<td>38.80</td>
<td>PKU Cooler 15 [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1

amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*1754.98</td>
<td>38.80</td>
<td>PKU Lophlex Sensation 20 [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*1001.21</td>
<td>38.80</td>
<td>PKU Lophlex LQ 10 [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouch

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*1466.15</td>
<td>38.80</td>
<td>PKU Air 15 [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*1000.43</td>
<td>38.80</td>
<td>PKU Lophlex LQ 10 [SB]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*1466.95</td>
<td>38.80</td>
<td>PKUexpress 15 [VF]</td>
</tr>
</tbody>
</table>

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*834.51</td>
<td>38.80</td>
<td>XP Maxamaid [SB]</td>
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</tbody>
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amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8</td>
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amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans

<table>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4</td>
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<td>PKU Cooler 20 [VF]</td>
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amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL

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<tr>
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<tr>
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</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**

Note: Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**Restricted benefit**

Phenylketonuria

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE**

Restricted benefit

Tyrosinaemia

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<td>TYR cooler 15 [VF]</td>
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<td>38.80</td>
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<tr>
<td>TYR express 15 [VF]</td>
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<td>5</td>
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<td>*3888.75</td>
<td>38.80</td>
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<tr>
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<td>38.80</td>
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<td>Amino Acid Formula</td>
<td>Max Qty Packs</td>
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<td>DPMQ</td>
<td>MRVSN</td>
<td>Brand Name and Manufacturer</td>
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<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine Powder for Oral Liquid, 500 g</strong></td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*2579.95</td>
<td>38.80</td>
<td>XPhen, Tyr Maxamum [SB]</td>
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<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine Powder for Oral Liquid, 400 g</strong></td>
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### Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine

#### Note

Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

#### Restricted benefit

Tyrosinaemia

<table>
<thead>
<tr>
<th>Amino Acid Formula</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine Powder for Oral Liquid, 30 x 87 mL Sachets</strong></td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2012.23</td>
<td>38.80</td>
<td>TYR Cooler 10 [VF]</td>
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### Amino Acid Formula with Vitamins and Minerals without Phenylalanine and Tyrosine

#### Restricted benefit

Maple syrup urine disease

<table>
<thead>
<tr>
<th>Amino Acid Formula</th>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine Oral Liquid, 125 mL, 30, 1</strong></td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*2953.90</td>
<td>38.80</td>
<td>TYR Lophlex LQ 20 [SB]</td>
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</table>

### Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine

#### Restricted benefit

Maple syrup urine disease

<table>
<thead>
<tr>
<th>Amino Acid Formula</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine Powder for Oral Liquid, 400 g</strong></td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*3888.75</td>
<td>38.80</td>
<td>MSUD Cooler 20 [VF]</td>
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<table>
<thead>
<tr>
<th>Amino Acid Formula</th>
<th>Max Qty Packs</th>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>5</td>
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<td>*2012.23</td>
<td>38.80</td>
<td>MSUD Cooler 10 [VF]</td>
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### Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine

#### Restricted benefit

Maple syrup urine disease

<table>
<thead>
<tr>
<th>Amino Acid Formula</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine Powder for Oral Liquid, 30 x 87 mL Sachets</strong></td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2953.95</td>
<td>38.80</td>
<td>MSUD Express 15 [VF]</td>
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### Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine

#### Restricted benefit

Maple syrup urine disease

<table>
<thead>
<tr>
<th>Amino Acid Formula</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine Oral Liquid, 125 mL, 30, 1</strong></td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*2953.90</td>
<td>38.80</td>
<td>MSUD Lophlex LQ 20 [SB]</td>
</tr>
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</table>
### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

#### Note
Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>MSUD gel [VF]</td>
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<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>MSUD Maxamum [SB]</td>
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<td>*2579.95</td>
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<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<th>MRVSN $</th>
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<tr>
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#### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

#### Restricted benefit
Maple syrup urine disease

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>MSUD Anamix Junior [SB]</td>
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<td>38.80</td>
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#### AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID

#### Restricted benefit
Phenylketonuria

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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#### AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

#### Restricted benefit
Phenylketonuria

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>PKU Anamix infant [SB]</td>
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<td>*663.95</td>
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#### AMINO ACID FORMULA WITHOUT PHENYLALANINE

#### Restricted benefit
Phenylketonuria
amino acid formula without phenylalanine 500 mg capsule, 200

8554F

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
16 5 .. *1209.07 38.80 Phlexy-10 [SB]

amino acid formula without phenylalanine powder for oral liquid, 30 x 20 g sachets

2347M

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
7 5 .. *1385.45 38.80 Phlexy-10 Drink Mix [SB]

amino acid formula without phenylalanine 1 g tablet, 75

8678R

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
24 5 .. *1351.39 38.80 Phlexy-10 [SB]

- AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

- ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

- ARGinine WITH CARBOHYDRATE

- CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

- CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Note: Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

Restricted benefit

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.
carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories powder for oral liquid, 30 x 21.5 g sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>basecal 100 [VF]</td>
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carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
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**CITRULLINE**

**Note**
Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

**Restricted benefit**
Urea cycle disorders
Clinical criteria:
- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline 1 g tablet, 300

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
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<td>1</td>
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**CITRULLINE WITH CARBOHYDRATE**

**Note**
Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**Restricted benefit**
Urea cycle disorders
Clinical criteria:
- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
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<td>*486.55</td>
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**CYSTINE WITH CARBOHYDRATE**

**Restricted benefit**
Pyridoxine non-responsive homocystinuria
cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>4</td>
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**DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**

**Restricted benefit**
Peroxisomal biogenesis disorders
docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>4</td>
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<td>docomega [VF]</td>
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</table>

**ESSENTIAL AMINO ACIDS FORMULA**

**Restricted benefit**
Gyrate atrophy of the choroid and retina

**Restricted benefit**
Urea cycle disorders
essential amino acids formula powder for oral liquid, 2 x 200 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tr>
<td>6</td>
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</table>

**ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C**

**Restricted benefit**
Gyrate atrophy of the choroid and retina

**Restricted benefit**
### Urea cycle disorders

**Essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5</td>
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<td>Dialamine [SB]</td>
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#### ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

**Restrict benefit**

- Gyrate atrophy of the choroid and retina
- Urea cycle disorders

**Essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>4</td>
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#### GLYCINE WITH CARBOHYDRATE

**Restrict benefit**

- Isovaleric academia

**Glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
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</table>

#### GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restrict benefit**

- Phenylketonuria

**Glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>1570.63</td>
<td></td>
<td>38.80</td>
<td>Camino Pro Bettermilk [QH]</td>
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</table>

**Glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>14</td>
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<td>860.73</td>
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<td>38.80</td>
<td>Camino Pro Complete [QH]</td>
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**Glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</table>

#### GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL cartons**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>PKU Glytactin RTD 15 [QH]</td>
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**Glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 30 x 250 mL cartons**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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#### GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restrict benefit**

- Tyrosinaemia

**Glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein equivalent oral liquid, 30 x 250 mL cartons**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</table>
Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 51 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
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<td>2068.43</td>
<td>PKU Bettermilk Lite [QH]</td>
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</table>

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
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<td>5</td>
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<td>1311.85</td>
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GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACID AND DOCOSAHEXANOIC ACID AND LOW PHENYLALANINE

Restricted benefit
Phenylketonuria

glycomacropeptide formula with long chain polyunsaturated fatty acid and docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit
Ketogenic diet

Clinical criteria:
• Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
• Patient must have a glucose transport protein defect; OR
• Patient must have pyruvate dehydrogenase deficiency.

Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit
Ketogenic diet

Clinical criteria:
• Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
• Patient must have a glucose transport protein defect; OR
• Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
<td>10185C</td>
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HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit
Ketogenic diet

Clinical criteria:
• Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
• Patient must have a glucose transport protein defect; OR
• Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.
- **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

  **Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Restricted benefit**
Ketogenic diet

**Clinical criteria:**
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.
KetoCal 4:1 should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist.

- **MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**

  **Restricted benefit**
  Ketogenic diet

  **Clinical criteria:**
  - Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
  - Patient must have a glucose transport protein defect; OR
  - Patient must have pyruvate dehydrogenase deficiency; OR
  - Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

- **PHENYLALANINE WITH CARBOHYDRATE**

  **Restricted benefit**
  Tyrosinaemia

- **PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

  **Restricted benefit**
  Phenylketonuria

  protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches
**SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**

**Restricted benefit**
Ketogenic diet

**Clinical criteria:**
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER**

**Restricted benefit**
Proven inborn errors of protein metabolism

**Clinical criteria:**
- Patient must be unable to meet their energy requirements with permitted food and formulae.

**TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER**

**Restricted benefit**
Proven inborn errors of protein metabolism

**Clinical criteria:**
- Patient must be unable to meet their energy requirements with permitted food and formulae.

**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

---

**Authority required (STREAMLINED)**

6156
Chylous ascites

6192
Chylothorax

6173
Fat malabsorption

**Clinical criteria:**
- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

**Authority required (STREAMLINED)**

6156
Hyperlipoproteinaemia type 1

**Authority required (STREAMLINED)**

6136
Long chain fatty acid oxidation disorders
triglycerides medium chain formula powder for oral liquid, 30 x 16 g sachets

9383W

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

4 5 . *230.19 38.80 MCT Pro-Cal [VF]

TYROSINE WITH CARBOHYDRATE

Restricted benefit
Phenylketonuria
tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets

9165J

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

4 5 . *486.55 38.80 Tyrosine 1000 [VF]

VALINE WITH CARBOHYDRATE

Restricted benefit
Maple syrup urine disease
valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets

9135T

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

4 5 . *486.55 38.80 Valine 50 [VF]

valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets

9434M

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

4 5 . *534.75 38.80 Valine 1000 [VF]

VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit
Dietary management of conditions requiring a highly restrictive therapeutic diet
Clinical criteria:
• Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND
• Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.
Population criteria:
• Patient must be aged 3 years or older.

vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets

10149E

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5 . 274.69 38.80 FruitiVits [VF]

VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit
Dietary management of conditions requiring a highly restrictive therapeutic diet
Clinical criteria:
• Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND
• Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.
Population criteria:
• Patient must be an infant or a child.

vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g

9328Y

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

6 5 . *364.57 38.80 Paediatric Seravit [SB]

WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

Authority required (STREAMLINED)
6190
Chronic renal failure
Clinical criteria:
• Patient must be an infant or a young child.

Population criteria:
• Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

*Authority required (STREAMLINED)*

**6190**

Chronic renal failure

**Population criteria:**
- Patient must be an infant or a young child.

**Clinical criteria:**
- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<td>*1007.95</td>
<td>Kindergen [SB]</td>
</tr>
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**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<td>2870C</td>
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<td>5</td>
<td>..</td>
<td>*1500.15</td>
<td>Renastart [VF]</td>
</tr>
</tbody>
</table>

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 10 x 100 g sachets**

<table>
<thead>
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<th>Max Qty Packs</th>
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<th>DPMQ</th>
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## Palliative Care

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<th>Section</th>
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<tbody>
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<td>ALIMENTARY TRACT AND METABOLISM</td>
<td>747</td>
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<tr>
<td>STOMATOLOGICAL PREPARATIONS</td>
<td>747</td>
</tr>
<tr>
<td>DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS</td>
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<tr>
<td>BELLADONNA AND DERIVATIVES, PLAIN</td>
<td>747</td>
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<td>PROPULSIVES</td>
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<tr>
<td>DRUGS FOR CONSTIPATION</td>
<td>747</td>
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<td>MUSCULO-SKELETAL SYSTEM</td>
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</table>
### ALIMENTARY TRACT AND METABOLISM

#### STOMATOLOGICAL PREPARATIONS

**STOMATOLOGICAL PREPARATIONS**

**Other agents for local oral treatment**

**BENZYDAMINE**

*Authority required (STREAMLINED)* 6197

- Painful mouth
- **Clinical criteria:**
  - Patient must be receiving palliative care.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difflam [IA]</td>
<td>24.18</td>
<td>25.39</td>
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**DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS**

**BELLADONNA AND DERIVATIVES, PLAIN**

**Belladonna alkaloids, semisynthetic, quaternary ammonium compounds**

**HYOSCINE BUTYLBROMIDE**

*Authority required (STREAMLINED)* 6207

- For use in patients receiving palliative care

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Buscopan [VZ]</td>
<td>99.31</td>
<td>38.80</td>
<td></td>
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</table>

**PROPULSIVES**

**Propulsives**

**METOCLOPRAMIDE**

*Authority required (STREAMLINED)* 6084

- Nausea or gastric stasis
- **Clinical criteria:**
  - Patient must be receiving palliative care.

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>Maxolon [IA]</td>
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**DRUGS FOR CONSTIPATION**

**DRUGS FOR CONSTIPATION**

**Contact laxatives**

**BISACODYL**

*Restricted benefit*

- Constipation
- **Clinical criteria:**
  - Patient must be receiving palliative care.

**bisacodyl 10 mg suppository, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Petrus Bisacodyl Suppositories [PP]</td>
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</table>

**bisacodyl 5 mg enteric tablet, 200**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lax-Tab [AE]</td>
<td>16.36</td>
<td>17.57</td>
<td></td>
</tr>
</tbody>
</table>
bisacodyl 10 mg suppository, 12

<table>
<thead>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
<td>21.43</td>
<td>22.64</td>
<td>Petrus Bisacodyl Suppositories [PP]</td>
</tr>
</tbody>
</table>

**Bulk-forming laxatives**

- **Rhamnus Frangula** + Sterculia

  - **Restricted benefit**
  - **Constipation**
  - **Clinical criteria:**
    - Patient must be receiving palliative care.

  **Rhamnus frangula 80 mg/g + Sterculia 620 mg/g granules, 500 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td></td>
<td>27.57</td>
<td>28.78</td>
<td>Normacol Plus [NE]</td>
</tr>
</tbody>
</table>

**Osmotically acting laxatives**

- **MacroGol-3350**

  - **Note** Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

  **Authority required (STREAMLINED)**

  **6170**
  - **Constipation**
  - **Clinical criteria:**
    - Patient must be receiving palliative care.

  **Macrogol-3350 1 g/g powder for oral liquid, 510 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td></td>
<td>26.23</td>
<td>27.44</td>
<td>OsmoLax [KY]</td>
</tr>
</tbody>
</table>

**Macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td></td>
<td>26.23</td>
<td>27.44</td>
<td>Herron ClearLax [ON]</td>
</tr>
</tbody>
</table>

- **Macrogol-3350 + Sodium Chloride + Bicarbonate + Potassium Chloride**

  **Authority required (STREAMLINED)**

  **6171**
  - **Constipation**
  - **Clinical criteria:**
    - Patient must be receiving palliative care.

  **Macrogol-3350 13.12 g + Sodium Chloride 350.7 mg + Potassium Chloride 46.6 mg (0.63 mmol potassium) + Sodium Bicarbonate 178.5 mg solution, 30 sachets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Macrogol-3350 13.12 g/25 mL + Sodium Chloride 350.7 mg/25 mL + Potassium Chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + Sodium Bicarbonate 178.5 mg/25 mL oral liquid, 500 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td></td>
<td>21.17</td>
<td>22.38</td>
<td>Movicol Liquid [NE]</td>
</tr>
</tbody>
</table>

**Enemas**

- **Bisacodyl**

  - **Restricted benefit**
  - **Constipation**
  - **Clinical criteria:**
    - Patient must be receiving palliative care.

  **Bisacodyl 10 mg/5 mL enema, 25 x 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td></td>
<td>38.50</td>
<td>38.80</td>
<td>Bisalax [AS]</td>
</tr>
</tbody>
</table>
**SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**

*Restricted benefit*

**Constipation**

**Clinical criteria:**
- Patient must be receiving palliative care.

**sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</thead>
<tbody>
<tr>
<td>5331N</td>
<td>2</td>
<td>3</td>
<td>*29.35</td>
<td>30.56</td>
<td>Micolette [AE]</td>
</tr>
</tbody>
</table>

**Peripheral opioid receptor antagonists**

**METHYLNALTREXONE**

*Authority required (STREAMLINED)*

**6180**

**Opioid-induced constipation**

**Clinical criteria:**
- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

**methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5423K</td>
<td>7</td>
<td>..</td>
<td>*263.77</td>
<td>38.80</td>
<td>Relistor [LM]</td>
</tr>
</tbody>
</table>

**METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>5424L</td>
<td>1</td>
<td>..</td>
<td>263.80</td>
<td>38.80</td>
<td>Relistor [LM]</td>
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</tbody>
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**MUSCULO-SKELETAL SYSTEM**

**ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS**

**ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS**

**Acetic acid derivatives and related substances**

**DICLOFENAC**

*Restricted benefit*

**Severe pain**

**Clinical criteria:**
- Patient must be receiving palliative care.

**diclofenac sodium 25 mg enteric tablet, 50**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>5361E</td>
<td>2</td>
<td>3</td>
<td>*14.03</td>
<td>15.24</td>
<td>APO-Diclofenac [TX]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonac 25 [RW]</td>
</tr>
<tr>
<td>Diclofenac Amneal [ED]</td>
</tr>
<tr>
<td>Diclofenac Sandoz [SZ]</td>
</tr>
</tbody>
</table>

| B3.44 | *17.47 | 15.24 | Voltaren 25 [NV] |

**diclofenac sodium 50 mg enteric tablet, 50**

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5362F</td>
<td>1</td>
<td>3</td>
<td>13.14</td>
<td>14.35</td>
<td>APO-Diclofenac [TX]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Clonac 50 [RW]</td>
</tr>
<tr>
<td>Diclofenac Amneal [ED]</td>
</tr>
<tr>
<td>Diclofenac Sandoz [SZ]</td>
</tr>
</tbody>
</table>

| B3.46 | 16.60 | 14.35 | Voltaren 50 [NV] |

**diclofenac sodium 100 mg suppository, 20**

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5363G</td>
<td>2</td>
<td>3</td>
<td>*27.51</td>
<td>28.72</td>
<td>Voltaren 100 [NV]</td>
</tr>
</tbody>
</table>

**INDOMETHACIN**

*Restricted benefit*

**Severe pain**

**Clinical criteria:**
- Patient must be receiving palliative care.
### MUSCULO-SKELETAL SYSTEM

#### Indomethacin

**indomethacin 25 mg capsule, 50**

<table>
<thead>
<tr>
<th>Brand/Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthrexin [AF]</td>
<td>*16.69</td>
<td>17.90</td>
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<tr>
<td><strong>Max Qty Packs</strong></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>No. of Rpts</strong></td>
<td>3</td>
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</table>

**indomethacin 100 mg suppository, 20**

<table>
<thead>
<tr>
<th>Brand/Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indocid [AS]</td>
<td>*25.07</td>
<td>26.28</td>
</tr>
<tr>
<td><strong>Max Qty Packs</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>No. of Rpts</strong></td>
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</tr>
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</table>

### Propionic acid derivatives

#### Ibuprofen

**Ibuprofen 400 mg tablet, 30**

<table>
<thead>
<tr>
<th>Brand/Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>APO-Ibuprofen 400 [TX]</td>
<td>*16.84</td>
<td>18.05</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
<td>3</td>
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</tr>
</tbody>
</table>

#### Naproxen

**Naproxen 125 mg/5 mL oral liquid, 474 mL**

<table>
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<tr>
<th>Brand/Manufacturer</th>
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<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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</table>

**Naproxen 250 mg tablet, 50**

<table>
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<tr>
<th>Brand/Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inza 250 [AF]</td>
<td>*18.35</td>
<td>19.56</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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**Naproxen 750 mg modified release tablet, 28**

<table>
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<tr>
<th>Brand/Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proxen SR 750 [IY]</td>
<td>*1.06</td>
<td>17.58</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**Naproxen 500 mg tablet, 50**

<table>
<thead>
<tr>
<th>Brand/Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inza 500 [AF]</td>
<td>*1.12</td>
<td>17.58</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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</table>

**Naproxen 1 g modified release tablet, 28**

<table>
<thead>
<tr>
<th>Brand/Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proxen SR 1000 [IY]</td>
<td>*1.12</td>
<td>18.77</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

### Note

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Severe pain

**Clinical criteria:**

- Patient must be receiving palliative care.

---

Schedule of Pharmaceutical Benefits – November 2017
### NERVOUS SYSTEM

#### ANALGESICS

##### MORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

**Authority required**

Chronic severe disabling pain

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

**MORPHINE sulfate 200 mg modified release tablet, 28**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>116.58</td>
<td>38.80</td>
<td>MS Contin [MF]</td>
</tr>
</tbody>
</table>

### NERVOUS SYSTEM

#### ANALGESICS

##### OPIOIDS

Natural opium alkaloids

- **MORPHINE**

  - Caution The risk of drug dependence is high.
  - Note Telephone approvals are limited to 1 month's therapy.

  **Authority required**

  Chronic severe disabling pain

  **Clinical criteria:**

  - Patient must be receiving palliative care, **AND**
  - The condition must be unresponsive to non-opioid analgesics.

- **MORPHINE sulfate 10 mg tablet, 20**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>18.61</td>
<td>19.82</td>
<td>Sevredol [MF]</td>
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</table>

- **MORPHINE sulfate 20 mg tablet, 20**

<table>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>19.43</td>
<td>20.64</td>
<td>Sevredol [MF]</td>
</tr>
</tbody>
</table>

- **FENTANYL**

  - Caution The risk of drug dependence is high.
  - Note Telephone approvals are limited to 1 month's therapy.

  **Authority required**

  Breakthrough pain

  **Clinical criteria:**

  - Patient must have cancer, **AND**
  - Patient must have pain directly attributable to cancer, **AND**
  - Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
  - Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; **OR**
  - The treatment must be used as short acting opioids are considered clinically inappropriate; **OR**
  - Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

  **Treatment criteria:**

  - Patient must be undergoing palliative care.
### NERVOUS SYSTEM

**FENTANYL Lozenge 1600 micrograms (as citrate), 9**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5406M</td>
<td>1</td>
<td></td>
<td>96.35</td>
<td>38.80</td>
<td></td>
<td>Actiq [TB]</td>
</tr>
</tbody>
</table>

**Fentanyl 600 microgram sublingual tablet, 10**

<table>
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<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10604D</td>
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<td></td>
<td>87.21</td>
<td>38.80</td>
<td></td>
<td>Abstral [FK]</td>
</tr>
</tbody>
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**FENTANYL Lozenge 200 micrograms (as citrate), 9**

<table>
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<td>96.35</td>
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<td>Actiq [TB]</td>
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**Fentanyl 100 microgram sublingual tablet, 10**

<table>
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<tbody>
<tr>
<td>10601Y</td>
<td>2</td>
<td></td>
<td>*160.32</td>
<td>38.80</td>
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<td>Abstral [FK]</td>
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**FENTANYL Lozenge 800 micrograms (as citrate), 9**

<table>
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<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5404K</td>
<td>1</td>
<td></td>
<td>96.35</td>
<td>38.80</td>
<td></td>
<td>Actiq [TB]</td>
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</table>

**Fentanyl 800 microgram sublingual tablet, 10**

<table>
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<th>Code</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10612M</td>
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<td></td>
<td>87.21</td>
<td>38.80</td>
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<td>Abstral [FK]</td>
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**FENTANYL Lozenge 1200 micrograms (as citrate), 9**

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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5405L</td>
<td>1</td>
<td></td>
<td>96.35</td>
<td>38.80</td>
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<td>Actiq [TB]</td>
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**Fentanyl 200 microgram sublingual tablet, 10**

<table>
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<th>Code</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>*160.32</td>
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**Fentanyl 400 microgram sublingual tablet, 10**

<table>
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<th>Code</th>
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<tr>
<td>10603C</td>
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<td>Abstral [FK]</td>
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**Fentanyl 300 microgram sublingual tablet, 10**

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<th>Brand Name and Manufacturer</th>
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<td>38.80</td>
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<td>Abstral [FK]</td>
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**FENTANYL Lozenge 600 micrograms (as citrate), 9**

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**FENTANYL Lozenge 400 micrograms (as citrate), 9**

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</table>

### FENTANYL

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Breakthrough pain

**Clinical criteria:**

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; **OR**

752 Schedule of Pharmaceutical Benefits – November 2017
• The treatment must be used as short acting opioids are considered clinically inappropriate; OR
• Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:
• Patient must be undergoing palliative care.

**Fentanyl 400 microgram orally disintegrating tablet, 4**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**Fentanyl 600 microgram orally disintegrating tablet, 4**

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**Fentanyl 200 microgram orally disintegrating tablet, 4**

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**Fentanyl 800 microgram orally disintegrating tablet, 4**

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<td>..</td>
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**Fentanyl 100 microgram orally disintegrating tablet, 4**

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**Fentanyl Lozenge 800 micrograms (as citrate), 30**

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**Fentanyl 100 microgram sublingual tablet, 30**

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<th>Premium $</th>
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**Fentanyl 200 microgram sublingual tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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**Fentanyl 300 microgram sublingual tablet, 30**

<table>
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<th>Max Qty Packs</th>
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<td>38.80</td>
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</table>

**Fentora [TB]**

Caution: The risk of drug dependence is high.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note** Telephone approvals are limited to 1 months’ therapy.

**Fentanyl**

**Caution** The risk of drug dependence is high.

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**Note** Telephone approvals are limited to 1 months’ therapy.
**FENTANYL**

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**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note** Telephone approvals are limited to 1 months’ therapy.

**Authority required**
*Breakthrough pain*

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**
- Patient must be undergoing palliative care.

<table>
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<td>Max Qty Packs</td>
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<thead>
<tr>
<th>FENTANYL 800 microgram sublingual tablet, 30</th>
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<tr>
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<table>
<thead>
<tr>
<th>FENTANYL Lozenge 400 micrograms (as citrate), 30</th>
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</thead>
<tbody>
<tr>
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<table>
<thead>
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<th>FENTANYL Lozenge 1200 micrograms (as citrate), 30</th>
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<th>FENTANYL Lozenge 200 micrograms (as citrate), 30</th>
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<tbody>
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<td><strong>5409Q</strong></td>
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<table>
<thead>
<tr>
<th>FENTANYL 800 microgram orally disintegrating tablet, 28</th>
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<tbody>
<tr>
<td><strong>10738E</strong></td>
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<th>FENTANYL 100 microgram orally disintegrating tablet, 28</th>
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<tbody>
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<td>Max Qty Packs</td>
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**NERVOUS SYSTEM**

**Palliative Care  755**

<table>
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<tr>
<td>10713W</td>
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<td>38.80</td>
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<td>..</td>
<td>..</td>
<td>*431.58</td>
<td>38.80</td>
</tr>
</tbody>
</table>

**Diphenylpropylamine derivatives**

**METHADONE**

- **Caution** The risk of drug dependence is high.
- **Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.
- **Note** Telephone approvals are limited to 1 month’s therapy.

**Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Chronic severe disabling pain
Treatment Phase: Initial treatment, for up to 3 months

Clinical criteria:
- Patient must be receiving palliative care, AND
- The condition must be unresponsive to non-opioid analgesics.

**Methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>Aspen Methadone Syrup [QA]</td>
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**Oripavine derivatives**

**BUPRENORPHINE**

- **Caution** The risk of drug dependence is high.
- **Note** Telephone approvals are limited to 1 month’s therapy.

**Authority required**
Chronic severe disabling pain
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must be receiving palliative care, AND
- The condition must be unresponsive to non-opioid analgesics.
### NERVOUS SYSTEM

#### buprenorphine 10 microgram/hour patch, 2

<table>
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<tr>
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#### buprenorphine 40 microgram/hour patch, 2

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#### buprenorphine 30 microgram/hour patch, 2

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#### buprenorphine 20 microgram/hour patch, 2

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<tr>
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<td>*94.76</td>
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#### buprenorphine 25 microgram/hour patch, 2

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<td>*108.20</td>
<td>38.80</td>
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#### buprenorphine 5 microgram/hour patch, 2

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#### buprenorphine 15 microgram/hour patch, 2

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<td>*80.56</td>
<td>38.80</td>
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### OTHER ANALGESICS AND ANTIPYRETICS

#### Anilides

- **PARACETAMOL**
  - **Restricted benefit**
  - Analgesia or fever
  - **Clinical criteria:**
    - Patient must be receiving palliative care, **AND**
    - Patient must be intolerant to alternative therapy.

- **paracetamol 500 mg suppository, 24**

<table>
<thead>
<tr>
<th>Code</th>
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<th>DPMQ $</th>
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<td>Panadol [GC]</td>
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- **PARACETAMOL**
  - **Note** Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

- **paracetamol 665 mg tablet: modified release, 192**

<table>
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<th>Code</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>..</td>
<td>18.55</td>
<td>19.76</td>
<td>* Osteomol 665 Paracetamol [CR]</td>
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- **paracetamol 665 mg modified release tablet, 96**

<table>
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<th>DPMQ $</th>
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<tr>
<td>5343F</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*18.55</td>
<td>19.76</td>
<td>* APOHEALTH Osteo Relief Paracetamol 665 mg [TX]</td>
</tr>
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</table>

### ANTIPELLEPTICS

#### Benzodiazepine derivatives
### CLONAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Myoclonus

**Clinical criteria:**
- The treatment must be for prophylaxis or prevention of the indication, **AND**
- Patient must be receiving palliative care.

#### clonazepam 2 mg tablet, 100

<table>
<thead>
<tr>
<th>5338Y</th>
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<tr>
<td>1</td>
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<td>21.80</td>
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<td></td>
<td></td>
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<td>2.30</td>
<td>24.10</td>
<td>23.01</td>
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#### clonazepam 2.5 mg/mL oral liquid, 10 mL

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<tr>
<td>2</td>
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#### clonazepam 500 microgram tablet, 100

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<tbody>
<tr>
<td>1</td>
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<td>16.78</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1.84</td>
<td>18.62</td>
<td>17.99</td>
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### PSYCHOLEPTICS

#### ANXIOLYTICS

**Benzodiazepine derivatives**

### DIAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Anxiety

**Clinical criteria:**
- Patient must be receiving palliative care.

#### diazepam 5 mg tablet, 50

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<tr>
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<td>12.48</td>
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<tr>
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<td>2.19</td>
<td>14.67</td>
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#### diazepam 2 mg tablet, 50

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<tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td>5.32</td>
<td>19.25</td>
<td>15.14</td>
<td>* Serepax [QA]</td>
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### OXAZEPAM

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Anxiety

**Clinical criteria:**
- Patient must be receiving palliative care.

#### oxazepam 30 mg tablet, 25

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<tr>
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<td>*13.25</td>
<td>14.46</td>
<td>* Alepam 30 [AF]</td>
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<tr>
<td></td>
<td></td>
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<td>4.66</td>
<td>17.91</td>
<td>14.46</td>
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#### oxazepam 15 mg tablet, 25

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<td>*13.93</td>
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<td>5.32</td>
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<td>15.14</td>
<td>* Serepax [QA]</td>
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### HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**
**NITRAZEPAM**

*Note* No increase in the maximum number of repeats may be authorised.

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<tbody>
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**Nitrazepam 5 mg tablet, 25**

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<tbody>
<tr>
<td>2</td>
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<td>14.31</td>
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<tr>
<td>6.48</td>
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<td>15.52</td>
<td>* Mogadon [IA]</td>
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</table>

**TEMAZEPAM**

*Note* No increase in the maximum number of repeats may be authorised.

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**Temazepam 10 mg tablet, 25**

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<tbody>
<tr>
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<td>..</td>
<td>13.25</td>
<td>14.46</td>
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<tr>
<td>6.96</td>
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<td>14.46</td>
<td>* Temaze [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Temtabs [FM]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>* Normison [QA]</td>
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ELTROMBOPAG

Note: No applications for increased repeats will be authorised.

**Authority required**
Severe thrombocytopenia

**Treatment Phase: Initial treatment 1 - New patient**

**Clinical criteria:**
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**
- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application:
- (a) a platelet count of less than or equal to 20,000 million per L; OR
- (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
4. a copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note: Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note: Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note: Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

**Authority required**
Severe thrombocytopenia

**Treatment Phase: Initial treatment 2 - New patient**

**Clinical criteria:**
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**
- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application:
- (a) a platelet count of less than or equal to 20,000 million per L; OR
(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a
history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the
clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical
grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note**
Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note**
Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail
to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to
receive further PBS-subsidised treatment with either of these drugs.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone
by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to
Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be
forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

**Clinical criteria:**
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this
  condition under the Initial treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**
- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of
PBS-subsidised treatment with this drug,
  AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
  OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at
  least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must
be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form,
  and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note**
Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

**Note**
Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail
to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to
receive further PBS-subsidised treatment with either of these drugs.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe thrombocytopenia
Treatment Phase: Second or subsequent Continuing treatment

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated a continuing response to treatment with this drug, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
- Patient must be an adult.
For the purpose of this restriction, a continuing response to treatment with drug is defined as:
- (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug
- AND either of the following:
  - (b) a platelet count greater than or equal to 50,000 million per L OR
  - (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.
The platelet count must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

Note: Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note: Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note: Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Authority required
Severe thrombocytopenia
Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, AND
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
- Patient must be an adult.

Note: Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Eltrombopag 50 mg tablet, 28**

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**Eltrombopag 25 mg tablet, 28**

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<td>1483.55</td>
<td>Revolade [NV]</td>
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</table>

**ROMIPLOSTIM**

Authority required
Severe thrombocytopenia
Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must have had a splenectomy, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
• Patient must be an adult.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;
  (a) a platelet count of less than or equal to 20,000 million per L; OR
  (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week.

The authority application must be made in writing and must include:
  (1) a completed authority prescription form,
  (2) a signed patient acknowledgement,
  (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
  (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
  (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:
• The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
• Patient must not have had a splenectomy, AND
• Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, AND
• Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, AND
• Patient must be unsuitable for splenectomy due to medical reasons, AND
• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
• Patient must be an adult.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;
  (a) a platelet count of less than or equal to 20,000 million per L; OR
  (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week.

The authority application must be made in writing and must include:
  (1) a completed authority prescription form,
  (2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the
clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical
grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail
to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to
receive further PBS-subsidised treatment with either of these drugs.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on
1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

Clinical criteria:
• The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
• Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, AND
• Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this
  condition under the Initial treatment restriction, AND
• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
• Patient must be an adult.
For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of
  PBS-subsidised treatment with this drug,
  AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at
  least four (4) occasions, each at least one week apart.
The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient
and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.
Authority approval will not be given for doses higher than 10 micrograms/kg/week
Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must
be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form ,
  and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).
The platelet count must be no more than one month old at the time of application.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail
to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to
receive further PBS-subsidised treatment with either of these drugs.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on
1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:
• The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must have demonstrated a continuing response to treatment with this drug, AND
• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
• Patient must be an adult.
For the purpose of this restriction, a continuing response to treatment with drug is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.
The platelet count must be no more than one month old at the time of application.
The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.
Authority approval will not be given for doses higher than 10 micrograms/kg/week
Authority applications for second and subsequent periods of continuing therapy may be made by telephone

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.
Note Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.
Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

Clinical criteria:
• The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, AND
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
• Patient must be an adult.
Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Note No applications for increased repeats will be authorised.

romiplostim 250 microgram injection, 1 vial

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<td>Nplate [AN]</td>
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romiplostim 500 microgram injection, 1 vial

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<td>Nplate [AN]</td>
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</table>
**DARBEPOETIN ALFA**

**Authority required**
Anaemia associated with intrinsic renal disease

**Clinical criteria:**
- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

<table>
<thead>
<tr>
<th>Darbepoetin Alfa 60 microgram/0.3 mL injection, 0.3 mL syringe</th>
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<tbody>
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<td>Max Qty Packs</td>
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<tr>
<th>Darbepoetin Alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes</th>
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<td>Max Qty Packs</td>
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<th>Darbepoetin Alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes</th>
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<td>Max Qty Packs</td>
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<thead>
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<th>Darbepoetin Alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes</th>
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<th>Darbepoetin Alfa 40 microgram/0.4 mL injection, 0.4 mL syringe</th>
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<tr>
<td>6490M</td>
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<th>Darbepoetin Alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes</th>
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<th>Darbepoetin Alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes</th>
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<td>Max Qty Packs</td>
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<td>6321Q</td>
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<table>
<thead>
<tr>
<th>Darbepoetin Alfa 20 microgram/0.5 mL injection, 0.5 mL syringe</th>
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<td>6488L</td>
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<th>Darbepoetin Alfa 80 microgram/0.4 mL injection, 0.4 mL syringe</th>
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<tr>
<td>6438W</td>
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<table>
<thead>
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<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>6493R</td>
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**BLOOD AND BLOOD FORMING ORGANS**

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

<table>
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<tr>
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<tr>
<td>6492Q</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*2536.59 Aranesp SureClick [AN]</td>
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**EPOETIN ALFA**

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>6205N</td>
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<td>..</td>
<td>*666.05 Eprex 3000 [JC]</td>
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</table>

**epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>6303R</td>
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<td>5</td>
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<td>*1239.53 Eprex 6000 [JC]</td>
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**epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes**

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<tr>
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<tbody>
<tr>
<td>6207Q</td>
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<td>*1918.93 Eprex 10000 [JC]</td>
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**epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

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<tbody>
<tr>
<td>6305W</td>
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<td>*1593.67 Eprex 8000 [JC]</td>
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**epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

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<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>6206P</td>
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**epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes**

<table>
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<th>DPMQ $</th>
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**epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
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<td>*1051.63 Eprex 5000 [JC]</td>
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**epoetin alfa 40 000 units/mL injection, 1 mL syringe**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tbody>
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**epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes**

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<tbody>
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<td>*517.75 Eprex 2000 [JC]</td>
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</table>

**EPOETIN BETA**

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>6484G</td>
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<td>5</td>
<td>..</td>
<td>*1239.53 NeoRecormon [RO]</td>
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</table>
### EPOETIN LAMBDA

**Note** Epoetin lambda should only be administered by the intravenous route.

**Authority required**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### EPOETIN LAMBDA

<table>
<thead>
<tr>
<th>Item</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
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<td>268.59</td>
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CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Antihypertensives for pulmonary arterial hypertension

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and

methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe

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Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
CARDIOVASCULAR SYSTEM

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   a. RHC composite assessment; and
   b. ECHO composite assessment; and
   c. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
• The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment

**Clinical criteria:**
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

**Response to a PAH agent is defined as follows:**

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Subsequent Continuing treatment

Clinical criteria:
- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**ambrisentan 10 mg tablet, 30**

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**ambrisentan 5 mg tablet, 30**

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**BOSENTAN**

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.
CARDIOVASCULAR SYSTEM

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Appraisals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six month initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the table strength required for the patient.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 2 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, AND
- Patient must have mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments; AND
2. RHC composite assessment plus 6MWT; AND
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services.
CARDIOVASCULAR SYSTEM

weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)**

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as both at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafl, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap permissioned PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not recommence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT);

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

• Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
• Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

bosentan 125 mg tablet, 60

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**BOSENTAN**

*Caution* This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Applications for authorisation must be in writing and must include:**

(1) two completed authority prescription forms; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(i) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.
The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.
Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The test results provided must not be more than 2 months old at the time of application.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
CARDIOVASCULAR SYSTEM

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted will be returned to the PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001
**Authority required**

Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
• Patient must have been assessed by a physician at a designated hospital, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:
• Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
• Patient must have not responded to prior PBS-subsidised therapy with this agent, AND
• The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

bosentan 62.5 mg tablet, 60
6429J

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**EPOPROSTENOL**

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
• Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
• Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

**Clinical criteria:**
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
CARDIOVASCULAR SYSTEM

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalfal, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:
- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
An application for Subsequent Continuing treatment with a PAH agent should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:

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Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### epoprostenol 500 microgram injection, 1 vial

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### epoprostenol 1.5 mg injection, 1 vial

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<th>DPMQ $</th>
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### epoprostenol 500 microgram injection [1 vial] & (8) inert substance diluent [2 x 50 mL vials], 1 pack

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### epoprostenol 1.5 mg injection [1 vial] & (8) inert substance diluent [2 x 50 mL vials], 1 pack

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### ILOPROST

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase:** Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III drug-induced PAH, AND
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note** Special Pricing Arrangements apply.

**Authority required**
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catherisation (RHC); **OR**
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexinigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; **OR**
- Patient must have WHO Functional Class IV drug-induced PAH, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

• Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

• Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

• Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND

• The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.
The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment. AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition. AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions. AND

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment
Clinical criteria:
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Subsequent Continuing treatment
Clinical criteria:
• Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
• Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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- **MACITENTAN**

  Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

  Authority required

  Pulmonary arterial hypertension (PAH)

  Treatment Phase: Initial 1 (new patients)

  Clinical criteria:

  • Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
  • Patient must have been assessed by a physician at a designated hospital, AND
  • Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditable PAH; OR
  • Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
  • Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
  • Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
  • Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
  • The treatment must be the sole PBS-subsidised PAH agent for this condition.

  Applications for authorisation must be in writing and must include:

  (1) a completed authority prescription form; and
  (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

  (i) RHC composite assessment; and
  (ii) ECHO composite assessment; and
  (iii) 6 Minute Walk Test (6MWT); and
  (3) a signed patient acknowledgement.

  Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

  (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
  (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

  Test requirements to establish baseline for initiation of treatment are as follows:

  The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

  Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

  (1) RHC plus ECHO composite assessments;
  (2) RHC composite assessment plus 6MWT;
  (3) RHC composite assessment only.
CARDIOVASCULAR SYSTEM

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contra-indicated, details of the nature of the adverse event or contra-indication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase:** Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; **OR**
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; **OR**
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.
CARDIOVASCULAR SYSTEM

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Or for these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note: Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note: Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
Highly Specialised Drugs Program (Private Hospital)  799

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
**Riociguat**

*Caution* This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

*Note* Special Pricing Arrangements apply.

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**CTEPH** that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- **Clinical criteria:**
  - Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
  - The condition must be inoperable by pulmonary endarterectomy; **OR**
  - The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy,

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:

1. completed authority prescription forms sufficient for dose titration; and
2. a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgment form; and
4. confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment;
   - ECHO composite assessment;
   - 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient’s response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)
CARDIOVASCULAR SYSTEM

Treatment Phase: Grandfathered patients

Clinical criteria:
- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, AND
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, AND
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy.

Treatment criteria:
- Must be treated in a centre with expertise in the management of CTEPH.

Clinical criteria:
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:
- Patient must be aged 18 years or older.
- CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:
  - Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\text{*sec}\text{*cm}^{-5} measured at least 90 days after start of full anticoagulation; and
  - A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:
- RHC demonstrating a PVR of greater than 300 dyn\text{*sec}\text{*cm}^{-5} measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:(1) A completed authority prescription form; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(2) RHC composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

Authority required
Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, AND
- The treatment must be the sole PBS-subsidised agent for this condition.

Treatment criteria:
CARDIOVASCULAR SYSTEM

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**
- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

**Riociguat**

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**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
CARDIOVASCULAR SYSTEM

- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating improvement or stability of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost tromethamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)
Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; **OR**
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
  - The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
- (1) completed authority prescription forms sufficient for dose titration; and
- (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension associated with connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term PAH agent refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note: Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
• The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: First Continuing treatment**

**Clinical criteria:**

• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available...
Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**
- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalfil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 4 (Grandfathered patients)

**Clinical criteria:**
- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, AND
- Patient must be receiving treatment with this drug at the time of application, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
- Patient must have a documented history of a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have a documented history of failure to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. (1) a completed authority prescription form; and
2. (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessment, (2) ECHO composite assessment, and (3) 6 Minute Walk Test.
assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note No applications for increased repeats will be authorised.

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<th>Authority required</th>
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<td>Pulmonary arterial hypertension (PAH)</td>
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<td>Treatment Phase: Initial 5 (Grandfathered patients)</td>
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Clinical criteria:
- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, AND
- Patient must be receiving treatment with this drug at the time of application, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg as measured by RHC; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have a documented history of WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and

Highly Specialised Drugs Program (Private Hospital)
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
   (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
   (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
   (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiogram (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note No applications for increased repeats will be authorised.

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  - DPMQ $: ..
  - Brand Name and Manufacturer: Adempas [BN]

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  - 11035T
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  - No. of Rpts: ..
  - Premium $: 3482.57
  - DPMQ $: ..
  - Brand Name and Manufacturer: Adempas [BN]

- **riociguat 2 mg tablet, 42**
  - 11045H
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  - DPMQ $: ..
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  - Premium $: 3482.57
  - DPMQ $: ..
  - Brand Name and Manufacturer: Adempas [BN]

### SILDENAFIL

**Authority required**

Pulmonary arterial hypertension (PAH)

TREATMENT PHASE: INITIAL 1 (NEW PATIENTS)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.
In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats may be requested.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to...
connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a

(i) a completed authority prescription form; and
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisantan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Subsequent Continuing treatment
Clinical criteria:
- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note**: Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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### TADALAFIL

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase**: Initial 1 (new patients)

**Clinical criteria**:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Applications for authorisation must be in writing and must include:**

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.
Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Initial 2 (new patients)**

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catherisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, pulmonary artery-hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

- barrier pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised treatment with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note** Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

**Department of Human Services**

**Complex Drugs**

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:

**Department of Human Services**

**Complex Drugs**

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Subsequent Continuing treatment

Clinical criteria:
• Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
• Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agent should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
tadalafil 20 mg tablet, 56
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Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
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PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Acromegaly
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), AND
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, AND
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:
1) Growth hormone level greater than 2.5 mcg/L; and
2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:
a) two completed authority prescription forms ; and
b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
d) a recent result of the IGF-1 level and the date of assessment ; and
e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.
PEGVISOMANT

Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

**Authority required**

Acromegaly

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:
1) Growth hormone level greater than 2.5 mcg/L; and
2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:
- a) two completed authority prescription forms; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).
In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Acromegaly

**Treatment Phase: Grandfathering**

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, AND
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- Patient must have had a documented age- and sex- adjusted insulin-like factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN) prior to commencing non-PBS-subsidised treatment with this drug.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Treatment must be ceased if IGF-1 level is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acromegaly Pegvisomant Grandfather PBS Authority Application - Supporting Information Form; and
3. in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
4. a recent result of the IGF-1 level and the date of assessment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**HYPOTHALAMIC HORMONES**

**Somatostatin and analogues**

- **LANREOTIDE**

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**lanreotide 30 mg modified release injection [1 vial] (8) inert substance diluent [2 mL ampoule], 1 pack**

<table>
<thead>
<tr>
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### LANREOTIDE

**Authority required**

**Acromegaly**

**Clinical criteria:**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required**

**Functional carcinoid tumour**

**Clinical criteria:**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months’ therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

### OCTREOTIDE

**Authority required**

**Acromegaly**

**Clinical criteria:**
- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

**Functional carcinoid tumour**

**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
• The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

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**octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

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**octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

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**OCTREOTIDE**

**Authority required**

Acromegaly

**Clinical criteria:**

- The condition must be active, AND
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, AND
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, AND
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, AND
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, AND
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.
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### PASIREOTIDE

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia.

**Note** Special Pricing Arrangements apply.

**Authority required**

- Acromegaly

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

1. Growth hormone level is greater than 2.5 mcg/L; and
2. IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1. Growth hormone (GH) levels of less than 2.5 mcg/L; and
2. normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgment; and
- d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- e) a recent copy of GH and IGF-1 levels must be provided.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Authority required**

- Acromegaly

**Treatment Phase: Grandfathering treatment**

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.
Population criteria:
- Patient must be aged 18 years or older.
In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:
1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:
- a completed authority prescription form;
- a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgment; and
- in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required
Acromegaly
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:
- Patient must be aged 18 years or older.
In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:
1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

---

### Prescription Information

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<th>Premium $</th>
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### Coverage

- **ANTIINFECTIVES FOR SYSTEMIC USE**
- **ANTIBACTERIALS FOR SYSTEMIC USE**
- **MACROLIDES, LINCOSSAMIDES AND STREPTOGRAMINS**

---

Macrolides
AZITHROMYCIN

Authority required
Mycobacterium avium complex infection

Clinical criteria:
• The treatment must be for prophylaxis, AND
• Patient must be human immunodeficiency virus (HIV) positive, AND
• Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

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CLARITHROMYCIN

Authority required
Mycobacterium avium complex infection

clarithromycin 500 mg tablet, 100

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ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority required
Mycobacterium avium complex infection

Clinical criteria:
• Patient must be human immunodeficiency virus (HIV) positive.

rifabutin 150 mg capsule, 30

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ANTITBIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required
Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:
• Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

<table>
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RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

---

**RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

---

**VALACICLOVIR**

**Authority required**
Cytomegalovirus infection and disease

**Treatment Phase:** Prophylaxis

**Clinical criteria:**
- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

---

**VALGANCICLOVIR**

**Authority required**
Cytomegalovirus infection and disease

**Treatment Phase:** Prophylaxis
ANTIINFECTIVES FOR SYSTEMIC USE

Clinical criteria:
- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 450 mg tablet, 60

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valganciclovir 50 mg/mL powder for oral liquid, 100 mL

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Other antivirals

- DACLATASVIR
  - Note No increase in the maximum quantity or number of units may be authorised.
  - Note No increase in the maximum number of repeats may be authorised.
  - Note Special Pricing Arrangements apply.

  Authority required
  Chronic hepatitis C infection

  Clinical criteria:
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
  - The treatment must be limited to a maximum duration of 24 weeks.

  daclatasvir 60 mg tablet, 28

<table>
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<th>Brand Name and Manufacturer</th>
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- DACLATASVIR
  - Note No increase in the maximum quantity or number of units may be authorised.
  - Note No increase in the maximum number of repeats may be authorised.
  - Note Special Pricing Arrangements apply.

  Authority required
  Chronic hepatitis C infection

  Clinical criteria:
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
  - The treatment must be limited to a maximum duration of 12 weeks.

  daclatasvir 60 mg tablet, 28

<table>
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  daclatasvir 30 mg tablet, 28

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- GRAZOPREVIR + ELBASVIR
  - Note No increase in the maximum quantity or number of units may be authorised.
  - Note No increase in the maximum number of repeats may be authorised.
  - Note Special Pricing Arrangements apply.

  Authority required
  Chronic hepatitis C infection

  Clinical criteria:
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
  - The treatment must be limited to a maximum duration of 12 weeks.
ANTIINFECTIVES FOR SYSTEMIC USE

GRAZOPREVIR + ELBASVIR

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the mask in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 16 weeks.

LEDIPASVIR + SOFOSBUVIR

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
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LEDIPASVIR + SOFOSBUVIR

Note: No increase in the maximum quantity or number of units may be authorised.
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Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 16 weeks.

LEDIPASVIR + SOFOSBUVIR

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 24 weeks.
ANTIINFECTIVES FOR SYSTEMIC USE

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

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PARITAPREVI + RITONAVIR + OMBITASVIR & DASABUVIR

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28

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PARITAPREVI + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution: Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

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paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

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PARITAPREVI + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution: Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
### Antineoplastic and Immunomodulating Agents

#### Antineoplastic Agents

**Pyrimidine analogues**

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#### Sofosbuvir

- **Sofosbuvir 400 mg tablet, 28**
- **Sofosbuvir 400 mg tablet, 28**
- **Sofosbuvir + Velpatasvir**

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

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<tr>
<th>Product Details</th>
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AZACITIDINE

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Myelodysplastic syndrome
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
• The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
(d) a copy of the full blood examination report; and
(e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
(f) a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

Authority required
Chronic Myelomonocytic Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required
Acute Myeloid Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

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<td>* AZACITIDINE DR.REDDY’S [RI]</td>
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AZACITIDINE

Note: Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
• The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
• The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required
Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
• The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required
Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
• The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

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CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required
Kaposi sarcoma
Clinical criteria:
• The condition must be AIDS-related, AND
• Patient must have a CD4 cell count of less than 200 per cubic millimetre, AND
• The condition must include extensive mucocutaneous involvement.

Authority required
Kaposi sarcoma
Clinical criteria:
• The condition must be AIDS-related, AND
• Patient must have a CD4 cell count of less than 200 per cubic millimetre, AND
• The condition must include extensive visceral involvement.
doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

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<td>* Liposomal Doxorubicin SUN [RA]</td>
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**OTHER ANTINEOPLASTIC AGENTS**

**Monoclonal antibodies**

- **RITUXIMAB**
  
  **Note** Risk of end-organ damage or mortality includes a minimum of one of the following:
  - Glomerulonephritis with risk of progression
  - Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
  - Bronchial/subglottic obstruction
  - Pulmonary haemorrhage
  - Parenchymal lung disease
  - Sensory neural hearing loss
  - Recurrent sinonasal disease requiring recurrent surgical interventions
  - Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

  **Note** Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons:
  - Cyclophosphamide is contraindicated as per the TGA approved Product Information;
  - Cyclophosphamide is not recommended due to the need to preserve gonad function;
  - Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
  - Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
  - Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
  - Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

  **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

  Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

  Applications for authority to prescribe should be forwarded to:
  - Department of Human Services
  - Prior Written Approval of Complex Drugs
  - Reply Paid 9826
  - HOBART TAS 7001

  **Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

  **Authority required**

  Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

  **Treatment Phase: Induction of remission**

  **Clinical criteria:**
  - The treatment must be for the induction of remission, **AND**
  - Patient must not have previously received this drug for this condition; **OR**
  - Patient must have received this drug for this condition prior to 1 January 2016, **AND**
  - The treatment must in combination with glucocorticoids, **AND**
  - Patient must be at risk of end-organ damage or mortality, **AND**
  - Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

  Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

  This drug is not PBS-subsidised for maintenance of remission

  The authority application must be made in writing

  **Authority required**

  Severe active microscopic polyangiitis

  **Treatment Phase: Induction of remission**

  **Clinical criteria:**
  - The treatment must be for the induction of remission, **AND**
  - Patient must not have previously received this drug for this condition; **OR**
  - Patient must have received this drug for this condition prior to 1 January 2016, **AND**
  - The treatment must in combination with glucocorticoids, **AND**
  - Patient must be at risk of end-organ damage or mortality, **AND**
  - Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

  Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance therapy.
The authority application must be made in writing

**Authority required**
Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Re-induction of remission

**Clinical criteria:**
- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission
The authority application must be made in writing

**Authority required**
Severe active microscopic polyangiitis
Treatment Phase: Re-induction of remission

**Clinical criteria:**
- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.
The authority application must be made in writing

**rituximab 500 mg/50 mL injection, 50 mL vial**

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**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

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**IMMUNOSTIMULANTS**

**Colony stimulating factors**

**FILGRASTIM**

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving first-line chemotherapy for Hodgkin disease, AND
• Patient must have had a prior episode of febrile neutropenia; OR
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving chemotherapy for myeloma, AND
• Patient must have had a prior episode of febrile neutropenia, AND
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, AND
• Patient must have had a prior episode of febrile neutropenia; OR
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authority required
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.
• Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**
• The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**
• The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required**

Assisting bone marrow transplantation

**Clinical criteria:**
• Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**
• The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required**

Severe congenital neutropenia

**Clinical criteria:**
• Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, AND
• Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required**

Severe chronic neutropenia

**Clinical criteria:**
• Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
• Patient must have neutrophil dysfunction, AND
• Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
• Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required**

Chronic cyclical neutropenia

**Clinical criteria:**
• Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, AND
• Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
• Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

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**filgrastim 300 microgram/mL injection, 10 x 1 mL vials**

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**filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes**

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**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

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LENOGRASTIM

Authority required
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving first-line chemotherapy for Hodgkin disease, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required
Chemotherapy-induced neutropenia

Clinical criteria:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required**
Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**
- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required**
Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**
- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**LIPEGFILGRASTIM**

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**
Chemotherapy-induced neutropenia
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving first-line chemotherapy for Hodgkin disease, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

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**PEGFILGRASTIM**

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving chemotherapy for myeloma, **AND**
• Patient must have had a prior episode of febrile neutropenia, **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**

**Chemotherapy-induced neutropenia**

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

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**Interferons**

**INTERFERON ALFA-2A**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

**Chronic Myeloid Leukaemia (CML)**

**Clinical criteria:**
- The condition must be Philadelphia chromosome positive.
interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

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interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

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**INTERFERON ALFA-2B**

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Clinical criteria:**
- The condition must be Philadelphia chromosome positive.

**Authority required**

Malignant melanoma

**Clinical criteria:**
- The treatment must be as adjunctive therapy to current standard care, **AND**
- Patient must have undergone surgery, **AND**
- The condition must include nodal involvement.

interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL

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interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

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interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials

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interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial

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**INTERFERON GAMMA-1B**

**Authority required**

Chronic granulomatous disease

**Clinical criteria:**
- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.
Authority required
Chronic hepatitis C infection

Treatment criteria:
• Must be treated in an accredited treatment centre.

Population criteria:
• Patient must be aged 18 years or older, AND
• Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Clinical criteria:
• Patient must have compensated liver disease, AND
• Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
• Patient must have a contraindication to ribavirin, AND
• The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
• The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

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peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

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PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required
Chronic hepatitis C infection

Clinical criteria:
• Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
• Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
• The treatment must be limited to a maximum duration of 12 weeks.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

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Other immunostimulants

plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial

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**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**
- Patient must have severe active rheumatoid arthritis, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated or must be avoided, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

If methotrexate is contraindicated or must be avoided, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

If methotrexate is contraindicated or must be avoided, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug dose, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised. Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

- The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
  (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
  (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
  (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**

- Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
- Applications for authority to prescribe should be forwarded to: Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding
rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tocافتinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
- either of the following:
  - (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  - (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  - (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tolerixinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has not had a break in therapy of longer than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

For second and subsequent courses of PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For patients to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringe(s) with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Treatment of Adult Patients with Severe Active Rheumatoid Arthritis

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700.

Treatment Phase: Continuing treatment

**Authority required**
Severe active rheumatoid arthritis

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
- A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
  - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
  - a patient cannot trial and fail, or cease to respond by at least 20% from baseline;

- AND either of the following:
  - a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate an adequate response to at least 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

- Department of Human Services
- Complex Drugs
- HOBART TAS 7001

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond by at least 20% from baseline;

- AND either of the following:
  - a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 278.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**abatacept 250 mg injection, 1 vial**

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**ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Multiple sclerosis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not show continuing progression of disability while on treatment with this drug, AND
- Patient must not receive more than one PBS-subsidised treatment per year, AND
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
**HSD (Private)**

**Treatment criteria:**
- Must be treated by a neurologist.

**alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial**

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**ALEMTUZUMAB**

*Note* Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

*Note* Special Pricing Arrangements apply.

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Authority required**

**Multiple sclerosis**

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**
- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

**ECULIZUMAB**

*Note* At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

*Note* **WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

*Note* Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of:
- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;
- In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

*Note* The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

*Note* Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:
1. a platelet count of less than 150x10^9/L; and evidence of two of the following:
   - presence of schistocytes on blood film;
   - low or absent haptoglobin;
   - lactate dehydrogenase (LDH) above normal range;
2. in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND
3. evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
   - (a) kidney impairment as demonstrated by one of the following:
     - a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
     - a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
     - a sCr of greater than the age-appropriate ULN in paediatric patients; or
   - (b) onset of TMA-related neurological impairment;
   - (c) onset of TMA-related cardiac impairment;
   - (d) onset of TMA-related gastrointestinal impairment;
   - (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:
1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A detailed cover letter from the prescriber; and
5. A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
6. A measurement of body weight at the time of application; and
7. The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
8. In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment 1-balance of supply; and
9. A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
10. Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
11. For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.
**ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases;
- g) Active autoimmune diseases;
- h) Hematopoietic stem cell transplants;
- i) Active malignancy;
- j) Active malignancy;
- k) Active malignancy;
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- Y) Active malignancy;
Note: For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Note: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note: Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note: The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient’s prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber’s interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note: The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:
- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, AND
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
- Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
- a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
- b) an eGFR within +/- 25% from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

A treatment failure is defined as a patient who is:
(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and
(3) A detailed cover letter from the prescriber; and
(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
(5) A measurement of body weight at the time of application; and
(6) An identified genetic mutation, if applicable; and
(7) A family history of aHUS, if applicable; and
(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
(10) An inclusion of the individual consequences of recurrent disease, if applicable; and
(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

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**ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient’s prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber’s interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
- (2) One of the following:
  - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
  - b) an eGFR within +/- 25% from baseline; or
  - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:
- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

**Clinical criteria:**
- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; **OR**
- Patient must have severe TMA-related neurological impairment; **OR**
- Patient must have severe TMA-related gastrointestinal impairment; **OR**
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; **OR**
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); **OR**
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(2) One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to
      commencing treatment with eculizumab or
   b) an eGFR within +/- 25% from baseline; or
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment
failure is defined as a patient who is:
   (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal
      complications if originally presented; or
   (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab
      and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial
haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
   (1) A completed authority prescription form; and
   (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
   (3) A detailed cover letter from the prescriber; and
   (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate
      antibiotic prophylaxis has been prescribed; and
   (5) A measurement of body weight at the time of application; and
   (6) An identified genetic mutation, if applicable; and
   (7) A family history of aHUS, if applicable; and
   (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
   (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
   (10) An inclusion of the individual consequences of recurrent disease; and
   (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result),
      neurological impairment, gastrointestinal impairment or pulmonary impairment; and
   (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at
      the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of
      application; and
   (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence
      that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications
      that have significantly improved; and
   (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical
      evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response
assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond
to treatment with eculizumab.

Note All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ
damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence
in the short term in the absence of continued treatment with eculizumab:
   a) Evidence of a mutation known to confer a high risk of aHUS recurrence; and
   b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use
      of eculizumab; and
   c) Past family history of aHUS recurrence, especially in first-degree relatives; and
   d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:
   • Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this
     condition, AND
   • Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this
     condition, AND
   • Patient must have the following clinical conditions: (i) either significant haemolysis as measured by low/absent
     haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either
     platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count < 150
     x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy, AND
   • Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
   • Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in
     consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
   (1) Normalisation of haemolysis as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
   (2) One of the following:
      a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to
         commencing treatment with eculizumab or
      b) an eGFR within +/- 25% from baseline; or
c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
(1) A completed authority prescription form(s); and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) A detailed cover letter from the prescriber; and
(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
(6) A measurement of body weight at the time of application, and
(7) An identified genetic mutation, if applicable; and
(8) A family history of aHUS if applicable; and
(9) A history of multiple episodes of aHUS following the treatment break, if applicable; and
(10) A history of kidney transplant if applicable (especially if required due to aHUS); and
(11) An inclusion of the individual consequences of recurrent disease; and
(12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
(13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
(14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note**
A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note**
Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

**Authority required**
Atypical haemolytic uraemic syndrome (aHUS)

**Clinical criteria:**
- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
(2) One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   b) an eGFR within +/- 25% from baseline; or
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
(3) A detailed cover letter from the prescriber; and
(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
(5) A measurement of body weight at the time of application; and
(6) An identified genetic mutation, if applicable; and
(7) A family history of aHUS, if applicable; and
(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
(9) A history of kidney transplant if applicable (especially if required due to aHUS); and
(10) An inclusion of the individual consequences of recurrent disease, if applicable; and
(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

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### EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

**Authority required**

Management of renal allograft rejection

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

Management of cardiac allograft rejection

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

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### MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

**Authority required**

Management of renal allograft rejection

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**Highly Specialised Drugs Program (Private Hospital)**

**Management of cardiac allograft rejection**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

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**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**WHO Class III, IV or V lupus nephritis**

**Treatment Phase:** Management

**Clinical criteria:**
- The condition must be proven by biopsy.

**Treatment criteria:**
- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 180 mg enteric tablet, 120**

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**mycophenolate 360 mg enteric tablet, 120**

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**Caution** Careful monitoring of patients is mandatory.

**Note** For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**Management of renal allograft rejection**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required**

**Management of cardiac allograft rejection**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

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mycophenolate Capsule 250 mg, 50
1837Q

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**NATALIZUMAB**

*Caution* Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required**
Clinically definite relapsing-remitting multiple sclerosis
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by a neurologist.

**Clinical criteria:**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

**Population criteria:**
- Patient must be aged 18 years or older.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Authority required**
Clinically definite relapsing-remitting multiple sclerosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial
9624M

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**SIROLIMUS**

*Caution* Careful monitoring of patients is mandatory.

**Authority required**
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

sirolimus 1 mg tablet, 100
6436R

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sirolimus 1 mg/mL oral liquid, 60 mL
6437T

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sirolimus 500 microgram tablet, 100
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sirolimus 2 mg tablet, 100
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Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Initial treatment authorisations under Initials 1 and Initial 2 will be limited to provide for a maximum of 16 week's therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For sequential and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for initial or continuing therapy for a minimum of 3 consecutive months and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

Treatment criteria:

• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

• Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND
• Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
• Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
• Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, AND
• Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
• Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), AND
• Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

• Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services
**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

**Note**

No applications for increased repeats will be authorised.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

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**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase:** Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, AND
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**
- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

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**Authority required**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Moderate to severe ulcerative colitis
Treatment Phase: Balance of supply

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction), AND
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:
- Patient must be aged 18 years or older.
- Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

Clinical criteria:
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, AND
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic baseline assessment is not available, AND
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:
- Patient must be 18 years of age or older.

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient’s condition; and
(ii) the date of commencement of this drug; and
(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient must have a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
**VEDOLIZUMAB**

Note: No applications for increased maximum quantities will be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Special Pricing Arrangements apply.

**Note: TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions (for example, adalimumab and infliximab), it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second
prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

(6) Patients ‘grandfathered’ onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

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**Severe Crohn disease**

**Treatment Phase: Initial treatment (new patient – initial 1)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
• Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND
• Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
• Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND
• Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:
• Patient must be aged 18 years or older.

Clinical criteria:
• Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
• Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND
• Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
• Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestine disease affecting more than 50 cm of the small intestine; OR
• Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iv) the date of the most recent clinical assessment; and
(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe Crohn disease
Treatment Phase: Change or Re-commencement of treatment (initial 2)
Clinical criteria:
- Patient must have a documented history of severe Crohn disease, AND
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; and
(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment; and
(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe Crohn disease
Treatment Phase: Initial PBS-subsidised treatment (Grandfather)
Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have a documented history of severe Crohn disease, AND
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

Population criteria:
Patient must be aged 18 years or older.

**Clinical criteria:**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment; and
  - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Authority required**
Severe Crohn disease

**Treatment Phase: Balance of supply**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**
- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Authority required
Severe Crohn disease
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have a documented history of severe Crohn disease, AND
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

Population criteria:
- Patient must be aged 18 years or older.

Clinical criteria:
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or an ostomy patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

vedolizumab 300 mg injection, 1 vial

Tumor necrosis factor alpha (TNF-) inhibitors

ADALIMUMAB

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Treatment criteria:
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
- Patient must have severe active juvenile idiopathic arthritis, AND
Highly Specialised Drugs Program (Private Hospital)

- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological...
therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Treatment criteria:
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Clinical criteria:
- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be under 18 years of age.
- For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
- The authority application must be made in writing and must include:
  1. a completed authority prescription form; and
  2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
- At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.
- Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.
- Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
- Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
- Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.
- If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.
- An adequate response to treatment is defined as:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following active joints, from at least 4, by at least 50%:
     i. elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     ii. shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
- Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
- A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
- From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
  1. continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
  2. fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
- A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
- A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
- A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
- There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to every course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). 

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**

**TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND
The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3. An acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note**

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826

HOBART TAS 7001

**Note**

**TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

1. continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
2. fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in the first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

1. **How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.**

   **(a) Initial treatment.**

   Applications for initial treatment should be made where:

   i. a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
   ii. a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
   iii. a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   iv. a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

   Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

   A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

   For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   **(b) Continuing treatment.**

   Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure...
uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

### Authority required
Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

1. (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
2. (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   1. (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

Highly Specialised Drugs Program (Private Hospital)
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have demonstrated an adequate response to treatment with etanercept, AND
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  1. elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  2. shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only one of the 3 bDMARDs at any one time. From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; or
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first treatment cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient...
will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment – balance of supply

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
• Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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- **INFLIXIMAB**

  Note No increase in the maximum number of repeats may be authorised.

Authority required
Acute severe ulcerative colitis

Treatment criteria:
• Must be treated by a gastroenterologist; OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

Clinical criteria:
• Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, AND
• Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

• Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, AND

• Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

  (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

  (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient’s medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

### INFILIXIMAB

**Note** Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

- Medicare Australia
- Prior Written Approval of Specialised Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy from an alternate agent (Initial 3); or

(iv) a patient wishes to continue treatment with the same TNF-alfa antagonist that they were previously treated with under the PBS (Initial 4); or

(v) a patient who is being treated with a TNF-alfa antagonist as a component of a biological combination therapy and wishes to continue with this combination therapy (Initial 5).

...
therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab. From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current course of treatment. Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle. A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives a maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing. (3) Baseline measurements to determine response. Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. (5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab. A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient who commenced treatment with adalimumab or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Authority required
Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.
Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The authority application must be made in writing.

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The authority application must be made in writing.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:
(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) is receiving treatment with infliximab at the time of application; and
(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient’s condition; and
(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

An adequate response is defined as:
(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

Continuing PBS-subsidised treatment under this restriction once only

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:
(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) is receiving treatment with infliximab at the time of application; and
(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

The authority application must be made in writing

### INFliximab 100 mg injection, 1 vial

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<tr>
<th>Brand Name and Manufacturer</th>
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### Note

**TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1);

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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**Authority required**

Moderate to severe Crohn disease

**Treatment Phase:** Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI

**Initial 1**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND
- Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription forms; and
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and
(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] OR a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Clinical criteria:
- Patient must have a documented history of moderate to severe Crohn disease, AND
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:
- Patient must be aged 6 to 17 years inclusive.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.
A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

**Treatment Phase:** Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**

- Patient must have a documented history of moderate to severe Crohn disease.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.
- Applications for authorisation must be made in writing and must include:
  - (a) a completed authority prescription form; and
  - (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
    - (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.
  - The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

Authority required  
Moderate to severe Crohn disease  
Treatment Phase: Balance of supply for a paediatric patient

Treatment criteria:  
- Must be treated by a gastroenterologist (code 87) or a consultant physician (general medicine specialising in gastroenterology (code 81)) or a consultant physician (general medicine specialising in gastroenterology (code 82)); OR  
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Clinical criteria:  
- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, AND  
- The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

Note  
Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1 kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

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From 1 September 2017, a patient may be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be deemed to have failed to respond to treatment with that drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be deemed to have failed to respond to treatment with that drug.
be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

**Note** No applications for increased maximum quantities will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iv) the date of the most recent clinical assessment; and
(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.
If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

**Treatment Phase: Change or Re-commencement of treatment (initial 2)**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, AND
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**
- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment; and
(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.
Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

### Authority required

**Severe Crohn disease**

**Treatment Phase: Balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment). **Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**
- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

### Authority required

**Severe Crohn disease**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**
- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
  - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy patient.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may
be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

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### INFLIXIMAB

**Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

**(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016**

(a) **Initial treatment.** Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) **Continuing treatment.**

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

**Swapping therapy.**

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved. Where the measurements timeframes vary, the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

**Baseline measurements to determine response.**

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response,
the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For second and subsequent treatment cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to infliximab or adalimumab only.

A patient is eligible for PBS-subsidised treatment with one of the TNF-alfa antagonists at any one time.

Infliximab and adalimumab are PBS-subsidised for moderate to severe disease, while only infliximab is PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has in a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping treatment' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 3). Treatment authors with that agent (Initial 1 and Initial 2) are limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. (2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate agent at any time,
regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with the drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response every 3 months of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured. (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

**Treatment Phase: Initial treatment (new patient or Recommission of treatment after more than 5 years break in therapy - Initial 1)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent; AND
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

**Population criteria:**

- Patient must be 6 years of age or older.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.
ANTEOPLASTIC AND IMMUNOMODULATING AGENTS

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

The authority application must be made in writing

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, AND
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**
- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy];

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Note**
No applications for increased repeats will be authorised.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Moderate to severe ulcerative colitis

**Treatment Phase: Balance of supply**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recomencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

**Population criteria:**
- Patient must be 6 years of age or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**infliximab 100 mg injection, 1 vial**

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**INFLIXIMAB**

**Authority required**
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated or not tolerated: (i) hydroxychloroquine at a dose of at least 1 mg/kg per day; and/or (ii) leflunomide at a dose of at least 10 mg daily; **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the application including severity.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised infliximab treatment was approved under the following treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
- If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
- Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding
(i) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response as specified in the restriction.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

### Authority required

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 22 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Note: Treatment of Adult Patients with Severe Active Rheumatoid Arthritis

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to that therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services.
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no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that rituximab.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencings patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment. AND
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have documented history of severe active rheumatoid arthritis, AND
- Patient must have demonstrated an adequate response to treatment with infliximab, AND
- Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a
disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tocilinitb, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient who has failed fewer than 5 bDMARDs and who has a break in PBS-subsidised therapy of more than 24 weeks (Initial 1); or

Rituximab patients:
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARD treatment with that agent.

Rituximab patients:
- a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
- a further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
- patients who have failed fewer than 5 bDMARDs and who have a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

ABATACEPT

Applications for new or re-commencing patients (Initial 2) [further details are under ‘Swapping therapy’ below]; or
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**infiximab 100 mg injection, 1 vial**

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**INFLIXIMAB**

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, AND
• Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND
• Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.
- The application must include details of the NSAIDs trialled, their doses and duration of treatment.
- If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
- If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
- If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
  - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - (ii) a completed BASDAI Assessment Form; and
  - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
  - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services.
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and Initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing).
with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:
• Patient must have active, or a documented history of active, ankylosing spondylitis, AND
• Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, AND
• The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have a documented history of active ankylosing spondylitis, AND
• Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
• Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist.
ANITIEOPLASTIC AND IMMUNOMODULATING AGENTS

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

For second and subsequent courses of PBS-subsidised treatment the drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.

For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Approval for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction

(c) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to re qualify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must re qualify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Ankylosing spondylitis**

**Treatment Phase:** Continuing treatment – balance of supply

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Severe psoriatic arthritis**

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### INFLIXIMAB

**Authority required**

Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; **OR**
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction, a biological agent is defined as a biological agent that is approved for the management of psoriatic arthritis by the TGA.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

- Severe psoriatic arthritis
- Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
• Patient must have a documented history of severe active psoriatic arthritis, **AND**
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
• Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
• Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

• Patient must be an adult.

**Treatment criteria:**

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis. Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment. Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of
at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date that the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

**How to prescribe biological agents for the treatment of severe active psoriatic arthritis.**

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Addendum: Updated 10/10/2016
(3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

infliximab 100 mg injection, 1 vial

6496X Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer

1 .. .. 534.87 Inflectra [PF] Remicade [JC]

* Renflexis [MK]

INFLIXIMAB

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at the end of the last subsidy, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under (4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2). 

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of the treatment within that Cycle. The Department of Human Services will review and either approve or deny the application.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuing treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a PASI assessment must be conducted after at least 12 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at the end of the last subsidy, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under (4) Swapping therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2). 

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).

Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of the treatment within that Cycle. The Department of Human Services will review and either approve or deny the application.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuing treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will
be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recomencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:
• Patient must have a documented history of severe chronic plaque psoriasis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.

Treatment criteria:
• Must be treated by a dermatologist.
For the purposes of this restriction ‘biological agent’ means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

**Severe chronic plaque psoriasis**

**Treatment Phase:** Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**
- Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; **AND**
- Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)
Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe chronic plaque psoriasis

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:
- Must be treated by a dermatologist.

Note
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.
- For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
- An adequate response to treatment is defined as:
  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.
- All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.
- Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
- Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.
- At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note
A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
- In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note
Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.
The most recent PASI assessment must be no more than 1 month old at the time of application.
Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.
The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND
• The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:
• Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

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Interleukin inhibitors

**ANAKINRA**

Note This drug is not PBS-subsidised for conditions other than CAPS.

Authority required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:
• Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
• Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient’s medical records.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

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**TOCILIZUMAB**

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Treatment criteria:
• Must be treated by a paediatric rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
• Patient must have severe active juvenile idiopathic arthritis, AND
• Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
• Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND
• Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
• Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note
Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24
weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

**Severe active juvenile idiopathic arthritis**

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. (completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
   (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
   (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
   (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
   (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD...
without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure...
uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:
- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 80 mg/4 mL injection, 4 mL vial

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**TOCILIZUMAB**

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Clinical criteria:
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which has methotrexate substituted for another DMARD as part of the 6 month intensive treatment with each of at least 2 DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
- Patient must receive no more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.
If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.
If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.
The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Support Information Form; and
(3) a signed patient acknowledgement.
At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.
If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.
Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive...
DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time. From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

**(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.**

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-
subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

**(2) Swapping therapy.**

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-
bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:
- an ESR no greater than 26 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:
- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Note: TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept, and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months may commence a new treatment cycle.

A patient who received PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatments will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure
uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

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**Authority required**

Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing Treatment – balance of supply

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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toxicilizumab 80 mg/4 mL injection, 4 mL vial

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**TOCILIZUMAB**

**Authority required**

Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have severe active rheumatoid arthritis, **AND**
• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
• Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; and
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive
Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1);
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(b) Continuing treatment.

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
 Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribing doctors may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be provided whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline,
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD
treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before...
swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

** Authority required **

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

** Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

** Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

** Note **

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

** Authority required **

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

** Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

** Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

** Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be
determined according to the reduction in the total number of active joints. Where the baseline is determined on total number
of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is
provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate
strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A
separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be
authorised.

Applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of
therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the
application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of
response to a minimum of 12 weeks of treatment with an initial treatment course.

If a patient fails to respond to treatment with tocilizumab under this restriction they will not be eligible to
receive further PBS-subsidised treatment with this drug for this condition.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological
disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term
bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists
(adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody
(rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated
kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs
at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate
a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a
disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a
response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-
subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please
contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is
sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A
patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a
further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who
has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for
treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD
treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding
rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than
24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent
(Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-
subsidiised therapy with that agent (Initial 2).

Initial applications for new or re- commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at
the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab,
etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the
dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a
minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment
restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**TOCILIZUMAB**

**Note**
TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or
(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the
date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.
For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.
Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.
Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.

(4) Recomencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Systemic juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:
- Patient must have been diagnosed with systemic juvenile idiopathic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR
- Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be under 18 years of age.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list:
  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and
(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
   (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
   (ii) details of prior treatment including dose and duration of treatment;
   (iii) pathology reports detailing CRP and platelet count where appropriate; and
(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note: To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

Note: Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:
• Patient must have a documented history of systemic juvenile idiopathic arthritis, AND
• Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND
• Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.
At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:
   (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
   (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
      - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
      - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:
   (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
   (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
   (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note: Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note:** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Systemic juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of systemic juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:
   (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
   (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
      - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
      - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:
   (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
   (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
   (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note**
An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
\textbf{Note} Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

\begin{center}
\textbf{USTEKINUMAB}
\end{center}

\textbf{Note} It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

\textbf{Note} No increase in the maximum number of repeats may be authorised.

\textbf{Note} Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001

\begin{center}
\textbf{TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE}
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The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab. From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy. For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S85 (General) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S100 (Highly Specialised Drugs) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy. A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients ‘grandfathered’ onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment...
限制。
一位患者可能仅一次资格接受PBS补助治疗此标准。PBS补助治疗在24周内被授权。完成初始PBS补助疗程后，进一步的治疗申请将基于标准评估。

'祖父母'安排只适用于第一治疗周期。对于第二和后续周期，需限制相关药物的治疗。

患者仅可一次资格接受PBS补助治疗。最多治疗24周。

治疗阶段：新患者-初始1

治疗标准：
- 必须由胃肠科医生[内部医学内科（Gastroenterology, code 81）]开具处方。
- 必须由胃肠科医生开具[内部医学内科（Gastroenterology, code 82）]处方。

临床标准：
- 患者必须有确认严重的克罗恩病，根据标准临床特征、内镜学特征或成像特征。
- 患者必须有无条件 response到前系统性治疗与糖皮质激素，持续6周；或
- 患者必须在治疗中断后有证明的严重反应。
- 患者必须为严重反应持续治疗。

权威需求

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND
- Patient must have failed to achieve an adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve an adequate response to prior systemic immunosuppressive therapy with mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must have (a) evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:
- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iv) the date of the most recent clinical assessment; and
(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.
Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

### Authority required

Severe Crohn disease

**Treatment Phase: Change or Re-commencement of treatment (initial 2)**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 811)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**
- Patient must be aged 18 years or older.
- Applications for authorisation must be made in writing and must include:
  - (a) two completed authority prescription forms; and
  - (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
    - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
    - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
    - (iii) the date of clinical assessment; and
  - (iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. The second prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

### ustekinumab 130 mg/26 mL injection, 26 mL vial

<table>
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**Calcineurin inhibitors**
## CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

**Authority required**

Management of transplant rejection

**Clinical criteria:**
- The treatment must be used by organ or tissue transplant recipients.

### cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules

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### CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

**Authority required**

Management of transplant rejection

**Clinical criteria:**
- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Severe atopic dermatitis**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies.

**Authority required**

**Severe psoriasis**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be ineffective to other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Authority required**

**Nephrotic syndrome**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must have failed prior treatment with steroids and cytostatic drugs; **OR**
- Patient must be intolerant to treatment with steroids and cytostatic drugs; **OR**
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Authority required**

**Severe active rheumatoid arthritis**

**Treatment Phase:** Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); **OR**
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Authority required**

**cyclosporin 50 mg capsule, 30**

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**cyclosporin 10 mg capsule, 60**

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cyclosporin 100 mg capsule, 30
6354K Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
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cyclosporin 25 mg capsule, 30
6352H Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
4 5 .. *141.19 * Cyclosporin Sandoz [SZ] * Neoral 25 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL
6125J Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
4 5 .. *1310.31 Neoral [NV]

**TACROLIMUS**
Caution Careful monitoring of patients is mandatory.

**Authority required**
Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**
- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

tacrolimus 2 mg capsule, 100
10879N Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *1047.15 Tacrolimus Sandoz [SZ]

tacrolimus 1 mg modified release capsule, 60
9682N Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *280.97 * ADVAGRAF XL [LQ] * Prograf XL [LL]

tacrolimus 1 mg capsule, 100
6216E Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *463.51 * Pacrolim [AF] * Prograf [LL]
  * Tacrolimus Sandoz [SZ]
  * Pharmacor Tacrolimus 1 [CR]
  * TACROLIMUS APOTEX [TX]

tacrolimus 5 mg modified release capsule, 30
9683P Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *787.61 * ADVAGRAF XL [LQ] * Prograf XL [LL]

tacrolimus 5 mg capsule, 50
6217F Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *1143.59 * Pacrolim [AF] * Prograf [LL]
  * Tacrolimus Sandoz [SZ]
  * Pharmacor Tacrolimus 5 [CR]
  * TACROLIMUS APOTEX [TX]

tacrolimus 750 microgram capsule, 100
10875J Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *397.15 Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule, 100
6328C Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *235.33 * Pacrolim [AF] * Prograf [LL]
  * Tacrolimus Sandoz [SZ]
  * Pharmacor Tacrolimus 0.5 [CR]
  * TACROLIMUS APOTEX [TX]

tacrolimus 500 microgram modified release capsule, 30
9681M Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer Brand Name and Manufacturer
2 5 .. *86.19 * ADVAGRAF XL [LQ] * Prograf XL [LL]

**Other immunosuppressants**

**LENALIDOMIDE**
Note Special Pricing Arrangements apply.

**Authority required**
Myelodysplastic syndrome
Treatment Phase: Initial treatment

**Clinical criteria:**
The treatment must be limited to a maximum duration of 16 weeks, AND
Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND
Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND
Patient must be red blood cell transfusion dependent.
Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.
Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:
1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.
Classification of a patient as red blood cell transfusion dependent requires that:
(i) the patient has been transfused within the last 8 weeks; and
(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
(d) a copy of the full blood examination report; and
(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
(g) a signed patient acknowledgement form.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, AND
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, AND
- Patient must not have progressive disease.
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.
The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.
The following evidence of response must be provided at each application:
(i) a haemoglobin level taken within the last 4 weeks; and
(ii) the date of the last transfusion; and
(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**Thalidomide treatment failure is defined as:**

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

**Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.**

**Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:**

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) duration of thalidomide and daily dose prescribed; and
- (4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Multiple myeloma**

**Treatment Phase:** Continuing PBS-subsidised treatment

**Clinical criteria:**
- Patient must have previously received an authority prescription for lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### lenalidomide 5 mg capsule, 21

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LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required
Multiple myeloma
Treatment Phase: Initial treatment

Clinical criteria:
• The condition must be newly diagnosed, **AND**
• The condition must be confirmed by a histological diagnosis, **AND**
• Patient must be ineligible for a primary stem cell transplantation, **AND**
• Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
• The treatment must be in combination with dexamethasone.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and
(3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:
(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Patient must be registered in the i-access risk management program.

Authority required
Multiple myeloma
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
• Patient must not have demonstrated progressive disease, **AND**
• Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
• The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.
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### POMALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
- (3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs
Multiple myeloma
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously been issued with an authority prescription for this drug, AND
• Patient must not have progressive disease, AND
• The treatment must be in combination with dexamethasone, AND
• Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note
Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

RITUXIMAB

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please...
Antineoplastic and Immunomodulating Agents

Contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

2. Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised...
TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP level measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Treatment criteria:

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

• Patient must have severe active rheumatoid arthritis, AND
• Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND
• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
• Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
• Patient must not receive more than 2 infusions of rituximab under this restriction, AND
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

• Patient must be aged 18 years or older.

For the purposes of this restriction “TNF” alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 2 infusions of rituximab under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; **AND**
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

The authority application must be made in writing and must include:
- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; **AND**
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
rituximab 500 mg/50 mL injection, 50 mL vial

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**THALIDOMIDE**

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

**Authority required**

- Multiple myeloma

thalidomide 50 mg capsule, 28

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thalidomide 100 mg capsule, 28

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**MUSCULO-SKELETAL SYSTEM**

**MUSCLE RELAXANTS**

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

*Other centrally acting agents*

**BACLOFEN**

**Authority required**

Severe chronic spasticity

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity of cerebral origin.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

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**BACLOFEN**

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required**

Severe chronic spasticity

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity of cerebral origin.
**Musculo-Skeletal System**

**Highly Specialised Drugs Program (Private Hospital)**

**Severe chronic spasticity**

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required**

**Severe chronic spasticity**

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required**

**Severe chronic spasticity**

**Clinical criteria:**
- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**Baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule**

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**Baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules**

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**DRUGS FOR TREATMENT OF BONE DISEASES**

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

**Bisphosphonates**

**Ibandronate**

**Authority required**

**Bone metastases**

**Clinical criteria:**
- The condition must be due to breast cancer.

**Ibandronate 6 mg/6 mL injection, 6 mL vial**

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**Pamidronate Disodium**

**Authority required**

**Hypercalcaemia of malignancy**

**Clinical criteria:**
- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

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**Pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

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**Pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

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**Pamidronate Disodium**

**Authority required**

**Hypercalcaemia of malignancy**

**Clinical criteria:**
- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Authority required**
Multiple myeloma

**Authority required**

Bone metastases

**Clinical criteria:**
- The condition must be due to breast cancer.

**Zoledronic Acid**

**Note** Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

**Authority required**

Multiple myeloma

**Authority required**

Bone metastases

**Clinical criteria:**
- The condition must be due to breast cancer.

**Authority required**

Bone metastases

**Clinical criteria:**
- The condition must be due to castration-resistant prostate cancer.

**Authority required**

Hypercalcaemia of malignancy

**Clinical criteria:**
- Patient must have a malignancy refractory to anti-neoplastic therapy.

**Zoledronic acid 4 mg/100 mL injection, 10 mL vial**

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**Zoledronic acid 4 mg/5 mL injection, 5 mL vial**

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**Zoledronic acid 4 mg/100 mL injection, 100 mL vial**

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**Dopa and dopa derivatives**

**Levodopa + Carbidopa Anhydrous**

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required**

Advanced Parkinson disease

**Clinical criteria:**
- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

**Levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

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**Apomorphine**

**Authority required**

Parkinson disease

**Clinical criteria:**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.
### NERVOUS SYSTEM

**Highly Specialised Drugs Program**  
**Private Hospital**

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#### apomorphine hydrochloride 100 mg/20 mL injection, 5 x 20 mL vials

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#### apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

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#### apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

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#### apomorphine hydrochloride 50 mg/10 mL injection, 5 x 10 mL syringes

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### PSYCHOLEPTICS

#### ANTIPSYCHOTICS

_Diazepines, oxazepines, thiazepines and oxepines_

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#### CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopincconnect.

**Authority required**

_Schizophrenia_

**Treatment Phase:** Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; **OR**
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

#### clozapine 200 mg tablet, 100

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#### clozapine 50 mg/mL oral liquid, 100 mL

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RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

MEPOLIZUMAB

Note: The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note: For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note: It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a ‘mepolizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this restriction. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial therapy, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients who have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or
www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** No increase in the maximum quantity or number of units may be authorised.  
**Note** No increase in the maximum number of repeats may be authorised.  
**Note** Special Pricing Arrangements apply.

**Authority required**  
Uncontrolled severe eosinophilic asthma  
Treatment Phase: Initial treatment  

**Treatment criteria:**  
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.  

**Clinical criteria:**  
- Patient must be under the care of the same physician for at least 12 months, **AND**  
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, **AND**  

- Clinical features:  
  (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms); or  
  (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or  
  (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**  

- Patient must have a duration of asthma of at least 1 year, **AND**  
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**  

- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**  

- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**  

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**  

- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

**Population criteria:**  
- Patient must be aged 12 years or older.  

Optimised asthma therapy includes:  
(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**  

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.  

- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.  

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:  
(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**  

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.  

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.  

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.  

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.  

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.  
Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.  

The authority application must be made in writing and must include:  
(a) a completed authority prescription form; and  
(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:  
(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and  
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and  
(iii) the signed patient or parent/guardian acknowledgement; and
RESPIRATORY SYSTEM

- MEPOLIZUMAB

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a ‘mepolizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.
An adequate response to mepolizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30 weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note
If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note
It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Uncontrolled severe eosinophilic asthma
Treatment Phase: Initial treatment - grandfather patients

Clinical criteria:
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND
- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, AND
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, AND
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, AND
- Patient must have demonstrated an adequate response to treatment with mepolizumab, AND
- The treatment must not be used in combination with omalizumab.

Population criteria:
- Patient must be aged 12 years or older.

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:
RESPIRATORY SYSTEM

omalizumab

mepolizumab 100 mg injection, 1 vial

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OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs

Note

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or (ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Note

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and
(iii) the signed patient or parent/guardian acknowledgement; and
(c) a copy of the pre-mepolizumab eosinophil pathology report.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
**Respiratory System**

**Highly Specialised Drugs Program (Private Hospital)**

**Severe chronic spontaneous urticaria**

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Severe chronic spontaneous urticaria**

**Treatment Phase: Continuing treatment**

**Treatment criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Severe chronic spontaneous urticaria**

**Treatment Phase: Grandfathering treatment**

**Clinical criteria:**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

**Note**
A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note**
Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Omalizumab 150 mg/mL injection, 1 mL syringe**

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**Omalizumab**

**Authority required**
Severe chronic spontaneous urticaria

**Treatment Phase: Continuing treatment**

**Treatment criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, AND
- Patient must receive more than 24 weeks per authorised course of treatment under this restriction.

**Note**
A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note**
Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Severe chronic spontaneous urticaria

**Treatment Phase: Grandfathering treatment**

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, AND
• Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition, AND
• Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, AND
• Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
• Must be treated by a clinical immunologist; OR
• Must be treated by an allergist; OR
• Must be treated by a dermatologist; OR
• Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:
1) a H2 receptor antagonist (150 mg twice per day); or
2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:
(i) demonstration of failure to achieve an adequate response to standard therapy; and
(ii) drug names and doses of standard therapies that the patient has failed; and
(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

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OMALIZUMAB

Note: Special Pricing Arrangements apply.

Authority required
Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, AND
• Patient must have a duration of asthma of at least 1 year, AND
• Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, AND
• Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, AND
• Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
• Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 6 to less than 12 years.

Treatment criteria:
• Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:
• Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:
(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least 6 months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND
(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment course), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND
(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:
(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(iii) acknowledgement signed by a parent or authorised guardian; and
(c) a copy of the IgE pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the prescriber's signature.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASThma

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment.
with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised omalizumab therapy. (a) Initial treatment: Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy. All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab. (b) Grandfather patients: Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details. (c) Continuing treatment: Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. (2) Baseline measurements to determine response: The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements. (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed. (4) Monitoring of patients: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur. Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe allergic asthma, AND
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. An adequate response to omalizumab treatment is defined as:
  (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
  (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR
  (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.
A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

(a) A completed authority prescription form; and
(b) A completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and
(c) A completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic
Note: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required
Uncontrolled severe allergic asthma
Treatment Phase: Initial and continuing treatment - balance of supply

Treatment criteria:
- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction or Grandfather treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing or Grandfather restrictions.

Note: Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing or grandfather restrictions may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Uncontrolled severe allergic asthma
Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have had, prior to commencement of omalizumab, a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, AND
- Patient must have received more than 24 weeks of treatment under this restriction, AND
- Patient must have demonstrated an adequate response to treatment.

Population criteria:
- Patient must be aged 6 to less than 12 years.

Treatment criteria:
- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:
- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:
(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND
(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient’s records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:
(i) a reduction in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire Interviewer Administered (ACQ-IA) score of at least 0.5; AND
(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or
Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

(iii) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

The assessment of the patient’s response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

Patients will be eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction only.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for an initial course of omalizumab of up to 24 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Paediatric Grandfather Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and
(iii) acknowledgement signed by a parent or authorised guardian.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:
Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of treatment with omalizumab, compared to the 12 months prior to commencement of omalizumab.
weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

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omalizumab 150 mg/mL injection, 1 mL syringe

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OMALIZUMAB

Note Special Pricing Arrangements apply.

Authority required
Uncontrolled severe allergic asthma
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
- Patient must be under the care of the same physician for at least 12 months, AND
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND
- Patient must have a duration of asthma of at least 1 year, AND
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, AND
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, AND
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, AND
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, AND
- Patient must not receive more than 28 weeks of treatment under this restriction, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

Population criteria:
- Patient must be aged 12 years or older.
- Optimum asthma therapy includes:
  (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
  (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(iii) the signed patient or parent/guardian acknowledgement; and
(c) the IgE pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a ‘mepolizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of...
therapy of omalizumab.

(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note
Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

*Note*
Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**
- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR
(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made
at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a ‘mepolizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
   i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
   ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
   iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum...
period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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<tr>
<td>Uncontrolled severe allergic asthma</td>
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<tr>
<th>Treatment Phase: Continuing treatment - balance of supply</th>
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<td>• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.</td>
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<th>Clinical criteria:</th>
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<td>• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, <strong>AND</strong></td>
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<td>• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.</td>
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Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

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omalizumab 150 mg/mL injection, 1 mL syringe

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**COUGH AND COLD PREPARATIONS**

**EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS**

**Mucolytics**

**DORNASE ALFA**

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

<table>
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<th>Population criteria:</th>
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<tr>
<td>• Patient must be 5 years of age or older.</td>
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<tr>
<td>• Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</td>
</tr>
<tr>
<td>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</td>
</tr>
<tr>
<td>Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.</td>
</tr>
<tr>
<td>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:</td>
</tr>
<tr>
<td>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</td>
</tr>
<tr>
<td>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</td>
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<tr>
<td>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.</td>
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<th>Clinical criteria:</th>
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<tr>
<td>• Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR</td>
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</table>
RESPIRATORY SYSTEM

• Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
• Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
• Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:
• Patient must be less than 5 years of age.
Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required
Cystic fibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND
• Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:
• Patient must be 5 years of age or older.
Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

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■ MANNITOL

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required
Cystic fibrosis
Clinical criteria:
• Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND
• Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:
• Patient must be 6 years of age or older.
Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:
(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

<table>
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■ OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

■ IVACAFTOR

Note Special Pricing Arrangements apply.
Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
RESPIRATORY SYSTEM

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Cystic fibrosis
Treatment Phase: Initial treatment - New patients

Clinical criteria:
- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:
- Patient must be aged 2 years or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
- Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, ritonavir, posaconazole, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.
- Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.
- Ivacaftor is not PBS-subsidised for this condition as a sole therapy.
- Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inhibitors:
  - Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
  - Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.
  - Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.
- The authority application must be in writing and must include:
  (1) a completed authority prescription form; and
  (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
  (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
  (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
  (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
  (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
  (7) a copy of a sweat chloride result; and
  (8) height and weight measurements at the time of application; and
  (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required
Cystic fibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:
- Patient must be aged 2 years or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month’s supply in order to enable the assessment to be repeated following resolution of the exacerbation. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, ibraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: ampnrenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcinil
- Weak CYP3A4 inducers: armodafinil, chinacine, pioglitazone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
3. the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older.

Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
4. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
5. height and weight measurements at the time of application; and
6. a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

### Ivacaftor 150 mg tablet, 56

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### IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have another gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 2 years old or younger.

Patients receiving PBS-subsidised Ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, ibraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: ampnrenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcinil
- Weak CYP3A4 inducers: armodafinil, chinacine, pioglitazone, rufinamide.

The authority application must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
(5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
(6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(7) a copy of a sweat chloride result; and
(8) height and weight measurements at the time of application; and
(9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the-home) in the previous 12 months.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Cystic fibrosis
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
• Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, AND
• Patient must not receive more than 24 weeks of treatment under this restriction, AND
• The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:
• Patient must be aged 2 years or older.
Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month’s supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nefavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, enalapril, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.
Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:
Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort
Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nelfinavir, nafcinil
Weak CYP3A4 inducers: admet farnill, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(5) height and weight measurements at the time of application; and
(6) a measurement of number of days of CF-related hospitalisation (including hospital-in-the-home) in the previous 6 months.

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Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Cystic fibrosis

**Treatment Phase: Initial treatment - Grandfather patients**

**Clinical criteria:**
- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, AND
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**
- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:
- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin
- Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
3. an acknowledgement signed by a parent, or authorised guardian if applicable; and
4. a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
5. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
6. a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
7. height and weight measurements at the time of application; and
8. height and weight measurements performed immediately prior to commencement of ivacaftor; and
9. a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
10. a measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the 6 months prior to the date of application; and
11. dates of prior ivacaftor therapy.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
### DEFERASIROX

**Note** Special Pricing Arrangements apply.

**Authority required**
- Chronic iron overload

**Clinical criteria:**
- Patient must have a disorder of erythropoiesis.

#### deferasirox 125 mg dispersible tablet, 28

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#### deferasirox 500 mg dispersible tablet, 28

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### DEFERIPRONE

**Authority required**
- Iron overload

**Clinical criteria:**
- Patient must have thalassaemia major, AND
- Patient must be unable to take desferrioxamine therapy.

#### deferiprone 500 mg tablet, 100

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#### deferiprone 100 mg/mL oral liquid, 250 mL

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### DESFERRIOXAMINE

**Authority required**
- Disorders of erythropoiesis

**Clinical criteria:**
- The condition must be associated with treatment-related chronic iron overload.

#### desferrioxamine mesilate 2 g injection, 1 vial

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**VARIOUS**

**Highly Specialised Drugs Program (Private Hospital)**

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**Drugs for treatment of hyperkalemia and hyperphosphatemia**

- **LANTHANUM**
  - **Authority required**
  - **Hyperphosphatemia**
  - **Treatment Phase: Initiation and stabilisation**
  - **Clinical criteria:**
    - The condition must not be adequately controlled by calcium, AND
    - Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
    - The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
    - The treatment must not be used in combination with any other non-calcium phosphate binding agents.
  - **Treatment criteria:**
    - Patient must be undergoing dialysis for chronic kidney disease.

- **LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**
  - 9635D
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
    - 2            | 5           | ..        | *524.41 | Fosrenol [ZI]               |

- **LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**
  - 9637F
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
    - 2            | 5           | ..        | *886.49 | Fosrenol [ZI]               |

- **LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**
  - 9636E
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
    - 2            | 5           | ..        | *788.23 | Fosrenol [ZI]               |

- **SEVELAMER**
  - **Authority required**
  - **Hyperphosphatemia**
  - **Treatment Phase: Initiation and stabilisation**
  - **Clinical criteria:**
    - The condition must not be adequately controlled by calcium, AND
    - Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
    - The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
    - The treatment must not be used in combination with any other non-calcium phosphate binding agents.
  - **Treatment criteria:**
    - Patient must be undergoing dialysis for chronic kidney disease.

- **Sevelamer hydrochloride 800 mg tablet, 180**
  - 9620H
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
    - 2            | 5           | ..        | *619.71 | Renagel [GZ]                |

- **SUCROFERRIC OXYHYDROXIDE**
  - **Authority required**
  - **Hyperphosphatemia**
  - **Treatment Phase: Initiation and stabilisation**
  - **Clinical criteria:**
    - The condition must not be adequately controlled by calcium, AND
    - Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
    - The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
    - The treatment must not be used in combination with any other non-calcium phosphate binding agents.
  - **Treatment criteria:**
    - Patient must be undergoing dialysis for chronic kidney disease.

- **Iron (as sucralfate) 500 mg tablet: chewable, 90**
  - 10230K
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
    - 2            | 5           | ..        | *790.75 | Velphoro [FN]               |
Highly Specialised Drugs Program (Public Hospital)

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NERVOUS SYSTEM

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DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
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COUGH AND COLD PREPARATIONS
EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS
OTHER RESPIRATORY SYSTEM PRODUCTS
OTHER RESPIRATORY SYSTEM PRODUCTS

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS
ALL OTHER THERAPEUTIC PRODUCTS
**ELTROMBOPAG**

*Note* No applications for increased repeats will be authorised.

**Authority required**
Severe thrombocytopenia

_Treatment Phase: Initial treatment 1 - New patient_

**Clinical criteria:**
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**
- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L; OR
(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

*Note* Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

*Note* Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

*Note* Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe thrombocytopenia

_Treatment Phase: Initial treatment 2 - New patient_

**Clinical criteria:**
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**
- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L; OR
b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

1. A completed authority prescription form,
2. A signed patient acknowledgement,
3. A completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
4. A copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. Where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note
Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note
Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, AND
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be an adult.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug, AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:

1. A completed authority prescription form, and
2. A completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
3. Copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The platelet count must not be more than one month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note
Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note
Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe thrombocytopenia
Treatment Phase: Second or subsequent Continuing treatment

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated a continuing response to treatment with this drug, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
- Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:
- (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug
- AND either of the following:
- (b) a platelet count greater than or equal to 50,000 million per L
  OR
- (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone

Note: Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note: Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note: Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Authority required
Severe thrombocytopenia
Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, AND
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
- Patient must be an adult.

Note: Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Eltrombopag 50 mg tablet, 28**

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**Eltrombopag 25 mg tablet, 28**

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**ROMIPLOSTIM**

Authority required
Severe thrombocytopenia
Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must have had a splenectomy, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L; OR
(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
4. a copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must not have had a splenectomy, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, AND
- Patient must be unsuitable for splenectomy due to medical reasons, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
- Patient must be an adult.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L; OR
(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: First Continuing treatment or Re-initiation of interrupted treatment

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, AND
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction, AND
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:
- Patient must be an adult.
For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug, AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.
The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses higher than 10 micrograms/kg/week.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).
The platelet count must be no more than one month old at the time of application.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required
Severe thrombocytopenia
Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:
- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must have demonstrated a continuing response to treatment with this drug, AND
• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

**Population criteria:**
• Patient must be an adult.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week
Authority applications for second and subsequent periods of continuing therapy may be made by telephone

**Note**
Romiplostim is not PBS-subsidised as an alternative to splenectomy.

**Note**
Authority applications for second and subsequent continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note**
Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
Special Pricing Arrangements apply.

**Authority required**
Severe thrombocytopenia
Treatment Phase: Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply

**Clinical criteria:**
• The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), AND
• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, AND
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**
• Patient must be an adult.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
No applications for increased repeats will be authorised.

### **Romiplostim 250 microgram injection, 1 vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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### **Romiplostim 500 microgram injection, 1 vial**

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</table>
**DARBEPOTIN ALFA**

**Authority required (STREAMLINED)**

6294

Anaemia associated with intrinsic renal disease

**Clinical criteria:**
- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe**

<table>
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<tr>
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**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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<tr>
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**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

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**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

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**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

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<th>DPMQ $</th>
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**darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe**

<table>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
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**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

<table>
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<th>DPMQ $</th>
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**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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**darbepoetin alfa 15 microgram/0.3 mL injection, 0.3 mL syringe**

<table>
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<th>DPMQ $</th>
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<td>Aranesp SureClick [AN]</td>
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</tbody>
</table>
**BLOOD AND BLOOD FORMING ORGANS**

**EPOETIN ALFA**

**Authority required (STREAMLINED)**

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**
- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**EPOETIN BETA**

**Authority required (STREAMLINED)**

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**
- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.
**EPOETIN LAMBDA**

Note: Epoetin lambda should only be administered by the intravenous route.

Authority required (STREAMLINED)

6245

Anaemia associated with intrinsic renal disease

Clinical criteria:
- Patient must require transfusion, AND
- Patient must have a haemoglobin level of less than 100 g per L, AND
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>5</td>
<td>..</td>
<td>*465.12</td>
<td>Novicrit [SZ]</td>
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</tbody>
</table>

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>..</td>
<td>*251.38</td>
<td>Novicrit [SZ]</td>
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</table>

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

<table>
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<td>*600.22</td>
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**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

<table>
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<th>DPMQ $</th>
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epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

<table>
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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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</table>

**METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**

*Authority required (STREAMLINED)*

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**
- Patient must require transfusion, AND
- Patient must have a haemoglobin level of less than 100 g per L, AND
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

methoxy polyethylene glycol-eopetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<td>*1100.88</td>
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methoxy polyethylene glycol-eopetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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methoxy polyethylene glycol-eopetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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<th>Premium</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<td>*350.72</td>
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methoxy polyethylene glycol-eopetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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methoxy polyethylene glycol-eopetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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<td>*851.22</td>
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methoxy polyethylene glycol-eopetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
<td>2</td>
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<td>*584.54</td>
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methoxy polyethylene glycol-eopetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe

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**CARDIOVASCULAR SYSTEM**

**ANTIHYPERTENSIVES**

**OTHER ANTIHYPERTENSIVES**

Antihypertensives for pulmonary arterial hypertension

**AMBRISENTAN**

*Caution* This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

*Authority required*

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   a. RHC composite assessment; and
   b. ECHO composite assessment; and
   c. 6 Minute Walk Test (6MWT); and
3. A signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. Mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. Where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

1. For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
2. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
3. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment;
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. A signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services Complex Drugs
CARDIOVASCULAR SYSTEM

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Clinical criteria:
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply
Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment

Clinical criteria:
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Subsequent Continuing treatment**

**Clinical criteria:**
- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition;
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### ambrisentan 10 mg tablet, 30

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<th>No. of Rpts</th>
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### ambrisentan 5 mg tablet, 30

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</tbody>
</table>

**BOSENTAN**

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Initial 1 (new patients)**

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:
  (1) two completed authority prescription forms; and
(2) the department's approved second authority prescription, which will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

CARDIOVASCULAR SYSTEM

The approved second authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 2 (new patients)**

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH, with a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; **OR**
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription will be limited to 1 month of therapy, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH...
agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply
Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment
Clinical criteria:
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition. **AND**

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### bosentan 125 mg tablet, 60

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* APO-BOSENTAN [GX]
* BOSENTAN-DRLA [RZ]
* Bosentan APOTEX [TX]
* Bosentan GH [GQ]
**BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Applications for authorisation must be in writing and must include:**

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
   3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or heritable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or heritable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or heritable PAH; **OR**
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; **OR**
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Applications for authorisation must be in writing and must include:**
(1) two completed authority prescription forms; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
CARDIOVASCULAR SYSTEM

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note: Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
• Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
• Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### Authority required
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
- Patient must have not responded to prior PBS-subsidised therapy with this agent, AND
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

### bosentan 62.5 mg tablet, 60

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### EPOPROSTENOL

**Authority required**
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

**Clinical criteria:**
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
4. for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats may be requested.
The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.
Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First
Continuing treatment - Balance of supply
Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment
Clinical criteria:
CARDIOVASCULAR SYSTEM

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

epoprostenol 500 microgram injection, 1 vial

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epoprostenol 1.5 mg injection, 1 vial

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epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack

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- ILOPROST

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with this agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III drug-induced PAH, AND
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.
CARDIOVASCULAR SYSTEM

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV drug-induced PAH, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised treatment with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
4. for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.
CARDIOVASCULAR SYSTEM

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to demonstrate stability or improvement of disease, OR
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs
**Authorised required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

**Clinical criteria:**

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**  Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**Authorised required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**

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**Highly Specialised Drugs Program (Public Hospital)**
• Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
• Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

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MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
• Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
• Patient must have been assessed by a physician at a designated hospital, AND
• Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditary PAH; OR
• Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
• Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
• Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
• Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.
Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:
For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 2 (new patients)**

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
CARDIOVASCULAR SYSTEM

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

(2) ECHO composite assessment only.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

• Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

• Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.
Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment

Clinical criteria:
- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment;
   - ECHO composite assessment;
   - 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

### Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
• The treatment must be the sole PBS-subsidised PAH agent for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalfil, macitentan, and riociguat.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### RIOCIUAT

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.
Approval for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats. The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Chronic thromboembolic pulmonary hypertension (CTEPH)**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**
- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Highly Specialised Drugs Program (Public Hospital)  1049

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; **OR**
- The condition must be recurrent or persistent following pulmonary endarterectomy.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; **and**
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form;
2. A completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:
   1. RHC composite assessment;
   2. ECHO composite assessment;
   3. A 6 Minute Walk Test (6MWT);
3. A signed patient acknowledgment form;
4. Confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; **or**
5. Confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; **or**
6. Confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

A maximum of 5 repeats will be authorised.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**
The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, AND

The treatment must be the sole PBS-subsidised agent for this condition.

**Treatment criteria:**
- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**
- Patient must be aged 18 years or older.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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### RIOCGUAT

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditable PAH; OR
• Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

• Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

• Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

• Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Highly Specialised Drugs Program (Public Hospital) 1051
CARDIOVASCULAR SYSTEM

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 2 (new patients)

Clinical criteria:
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension Initial PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambri sentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services.
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, and
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 6 Minute Walk Test (6MWT).

**Test requirements to establish response to treatment for continuation of treatment as follows:**

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

**Note** An application for First Continuing treatment with a PAH agent should be made two weeks prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Subsequent Continuing treatment

**Clinical criteria:**
- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 4 (Grandfathered patients)

**Clinical criteria:**
- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, **AND**
- Patient must be receiving treatment with this drug at the time of application, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a documented history of a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have a documented history of right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have a documented history of failure to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.
CARDIOVASCULAR SYSTEM

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. The test results provided must not be more than 2 months old at the time of application. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note No applications for increased repeats will be authorised.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 5 (Grandfathered patients)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition prior to 1 February 2017, AND
- Patient must be receiving treatment with this drug at the time of application, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have a documented history of WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have a documented history of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease as assessed by echocardiograph (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have a documented history of WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have a documented history of WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
• Patient must have a documented history of WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND

• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (ECHO composite assessment, plus a 6 minute walk test; ECHO composite assessment plus 6MWT; ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Approval for authority prescriptions will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 5 repeats.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. No applications for increased repeats will be authorised.

### riociguat 2 mg tablet, 84

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### riociguat 1.5 mg tablet, 84

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CARDIOVASCULAR SYSTEM

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**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase:** Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

**Idiopathic pulmonary arterial hypertension,** anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**Test requirements to establish baseline for initiation of treatment are as follows:**

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.
Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as at least 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested. The assessment of the patient’s response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedged pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiograph (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

• Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
• Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:
- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-
subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes
results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-
subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment
application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT
results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the
same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific
reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of
application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result
demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result
demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating
stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage
recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month
treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment
is required must cease PBS-subsidised therapy with this agent.
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate,
ambrisentan, tadalafil, macitentan, and riociguat.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease
associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

Note: Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note: Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

sildenafil 20 mg tablet, 90

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**TADALAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of the three tests above, where available:

1. RHC plus ECHO composite assessment; and
2. RHC composite assessment plus 6MWT; and
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.
CARDIOVASCULAR SYSTEM

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); **OR**
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; **OR**
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWTest); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

A maximum of 5 repeats may be requested.

The test results provided must not be more than 2 months old at the time of application.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Pulmonary arterial hypertension (PAH)**

Treatement Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
CARDIOVASCULAR SYSTEM

A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
• Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
• The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: First Continuing treatment

Clinical criteria:
• Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND
• Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND
• The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and  
(ii) ECHO composite assessment; and  
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:  
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:  
(1) RHC plus ECHO composite assessments plus 6MWT;  
(2) RHC plus ECHO composite assessments;  
(3) RHC composite assessment plus 6MWT;  
(4) ECHO composite assessment plus 6MWT;  
(5) RHC composite assessment only;  
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.  
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:  
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.  
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.  
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.  
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.  
A maximum of 5 repeats will be authorised.  
An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.  
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.  
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.  
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
### SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

#### Systemic Hormonal Preparations

**tadalafil 20 mg tablet, 56**

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### PEGVISOMANT

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

**Acromegaly**

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue. Somatostatin analogues include octreotide, lanreotide and pasireotide
- Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:
  1) Growth hormone level greater than 2.5 mcg/L; and
  2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN
- If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.
- If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.
- In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.
- Biochemical evidence of remission is defined as normalisation of sex- and age-adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) two completed authority prescription forms; and
b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
d) a recent result of the IGF-1 level and the date of assessment; and
e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide
No increase in the maximum quantity or number of units may be authorised for the loading dose.

**PEGVISOMANT**

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

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<td>Treatment Phase: Initial treatment</td>
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Clinical criteria:
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue. Somatostatin analogues include octreotide, lanreotide and pasireotide
- Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:
  1) Growth hormone level greater than 2.5 mcg/L;
  2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN
- If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.
- If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.
- In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.
- Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).
- Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.
- The authority application must be made in writing and must include:
  a) two completed authority prescription forms; and
  b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
  c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
  d) a recent result of the IGF-1 level and the date of assessment; and
  e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide
- No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.
- Somatostatin analogues include octreotide, lanreotide and pasireotide
- In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.
- Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).
In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Acromegaly
Treatment Phase: Grandfathering

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- Patient must have had a documented age- and sex-adjusted insulin-like factor 1 (IGF-1) concentration greater than 1.3 times upper limit of normal (ULN) prior to commencing non-PBS-subsidised treatment with this drug.

Somatostatin analogues include octreotide, lanreotide and pasireotide
In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age-adjusted insulin-like growth factor 1 (IGF-1). Treatment must be ceased if IGF-1 level is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Acromegaly Pegvisomant Grandfather PBS Authority Application - Supporting Information Form; and
3. in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
4. a recent result of the IGF-1 level and the date of assessment.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

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### pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

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**HYPOTHALAMIC HORMONES**

### Somatostatin and analogues

#### LANREOTIDE

**Authority required (STREAMLINED)**

7042

Acromegaly

**Clinical criteria:**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
• The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), AND
• The treatment must cease if IGF1 is not lower after 3 months of treatment, AND
• The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**lanreotide 30 mg modified release injection [1 vial] (8) and inert substance diluent [2 mL ampoule], 1 pack**

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### LANREOTIDE

**Authority required (STREAMLINED)**

**7025**

**Acromegaly**

**Clinical criteria:**
• The condition must be active, AND
• Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND
• The treatment must be after failure of other therapy including dopamine agonists; OR
• The treatment must be as interin treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
• The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND
• The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND
• The treatment must cease if IGF1 is not lower after 3 months of treatment, AND
• The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

**4575**

**Functional carcinoid tumour**

**Clinical criteria:**
• The condition must be causing intractable symptoms, AND
• Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
• Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
• The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

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**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

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**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

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### OCTREOTIDE

**Authority required (STREAMLINED)**

**7029**

**Acromegaly**

**Clinical criteria:**
• The condition must be controlled with octreotide immediate release injections, AND
• The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND
• The treatment must cease if IGF1 is not lower after 3 months of treatment, AND
• The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**
5901
Functional carcinoid tumour
Clinical criteria:
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

5906
Vasoactive intestinal peptide secreting tumour (VIPoma)
Clinical criteria:
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

• OCTREOTIDE

Authority required (STREAMLINED)

7028
Acromegaly
Clinical criteria:
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 times daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.
In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)

6390
Functional carcinoid tumour
Clinical criteria:
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

6369
Vasoactive intestinal peptide secreting tumour (VIPoma)
Clinical criteria:
- The condition must be causing intractable symptoms, **AND**
• Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
• Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
• The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months’ therapy.

**Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.**

**octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

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**octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

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**octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

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**PASIREOTIDE**

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly:

**Treatment Phase: Initial treatment**

**Clinical criteria:**

• Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
• Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
• The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
• The treatment must not be given concomitantly with PBS-subsidised pegvisomant. **AND**

**Population criteria:**

• Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. Failure to achieve biochemical control is defined as:

1) Growth hormone level is greater than 2.5 mcg/L; and
2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) a completed authority prescription form; and
b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
c) a signed patient acknowledgment; and
d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and

e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Acromegaly

Treatment Phase: Grandfathering treatment

Clinical criteria:
- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

Population criteria:
- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:
1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:
- a completed authority prescription form;
- a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- a signed patient acknowledgment; and
- in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:
- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:
1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

---

pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority required (STREAMLINED)
6356
Mycobacterium avium complex infection
Clinical criteria:
• The treatment must be for prophylaxis, AND
• Patient must be human immunodeficiency virus (HIV) positive, AND
• Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8
5616N

<table>
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CLARITHROMYCIN

Authority required (STREAMLINED)
5874
Mycobacterium avium complex infection

clarithromycin 500 mg tablet, 100
5624B

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ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority required (STREAMLINED)
6350
Mycobacterium avium complex infection
Clinical criteria:
• Patient must be human immunodeficiency virus (HIV) positive.

Authority required (STREAMLINED)
6356
Mycobacterium avium complex infection
Clinical criteria:
• The treatment must be for prophylaxis, AND
• Patient must be human immunodeficiency virus (HIV) positive, AND
• Patient must have CD4 cell counts of less than 75 per cubic millimetre.

rifabutin 150 mg capsule, 30
9541E

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ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required (STREAMLINED)
4972
Cytomegalovirus disease
Treatment Phase: Prophylaxis
Clinical criteria:
• Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)
4999
Cytomegalovirus disease
ANTIINFECTIVES FOR SYSTEMIC USE

Treatment Phase: Prophylaxis

Clinical criteria:
- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**ganciclovir 500 mg injection, 5 vials**

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**RIBAVIRIN**

Caution: Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note: No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

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**ribavirin 200 mg tablet, 28**

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**ribavirin 600 mg tablet, 28**

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**RIBAVIRIN**

Caution: Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note: No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**ribavirin 400 mg tablet, 28**

<table>
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<tr>
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**ribavirin 200 mg tablet, 28**

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**ribavirin 600 mg tablet, 28**

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**VALACICLOVIR**

Authority required (STREAMLINED)

5975

Cytomegalovirus infection and disease
ANTIINFECTIVES FOR SYSTEMIC USE

Treatment Phase: Prophylaxis
Clinical criteria:
- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

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**VALGANCICLOVIR**

**Authority required (STREAMLINED)**

4989
Cytomegalovirus infection and disease
Treatment Phase: Prophylaxis
Clinical criteria:
- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 450 mg tablet, 60

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valganciclovir 50 mg/mL powder for oral liquid, 100 mL

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**Other antivirals**

**DACLATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection
Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

daclatasvir 60 mg tablet, 28

<table>
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daclatasvir 30 mg tablet, 28

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**DACLATASVIR**

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection
Clinical criteria:
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

daclatasvir 60 mg tablet, 28

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ANTIINFECTIVES FOR SYSTEMIC USE

**daclatasvir 30 mg tablet, 28**

<table>
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**GRAZOPREVIR + ELBASVIR**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**grazoprevir 100 mg + elbasvir 50 mg tablet, 28**

<table>
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**GRAZOPREVIR + ELBASVIR**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

**ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28**

<table>
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**LEDIPASVIR + SOFOSBUVIR**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.
ANTIINFECTIVES FOR SYSTEMIC USE

**LEDIPASVIR + SOFOSBUVIR**

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

<table>
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<th>Authority required</th>
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<td>Clinical criteria:</td>
<td>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, <strong>AND</strong></td>
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<tr>
<td>Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>The treatment must be limited to a maximum duration of 24 weeks.</td>
<td></td>
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| Paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28 |
|-----------------|----------------------------------|
| Authority required | Chronic hepatitis C infection |
| Clinical criteria: | Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND** |
| Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND** |
| The treatment must be limited to a maximum duration of 12 weeks. |

**PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR**

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

Caution: Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Authority required</th>
<th>Chronic hepatitis C infection</th>
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<tbody>
<tr>
<td>Clinical criteria:</td>
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</tr>
<tr>
<td>Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, <strong>AND</strong></td>
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<td>The treatment must be limited to a maximum duration of 24 weeks.</td>
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<tr>
<td>Population criteria:</td>
<td>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each use an effective form of contraception if of child-bearing age.</td>
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| Paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 28 |
|-----------------|----------------------------------|
| Authority required | Chronic hepatitis C infection |
| Clinical criteria: | Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND** |
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| Population criteria: | Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each use an effective form of contraception if of child-bearing age. |

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**ANTIINFECTIVES FOR SYSTEMIC USE**

**PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN**

*Caution* Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

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- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

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**SOFOSBUVIR**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

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**SOFOSBUVIR + VELPATASVIR**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection
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- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

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**AZACITIDINE**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Clinical criteria:**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); **OR**
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
- a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; **OR**
- b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; **OR**
- c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; **OR**
- d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; **OR**
- e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; **OR**
- f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:
- a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; **OR**
- b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; **OR**
- c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; **OR**
- d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (d) a copy of the full blood examination report; and
- (e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- (f) a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

**Chronic Myelomonocytic Leukaemia**

**Clinical criteria:**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.
The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required
Acute Myeloid Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.
The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

Azacitidine 100 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>*Celazadine [JU]</td>
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<td>*Vidaza [CJ]</td>
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</table>

AZACITIDINE

Note: Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required
Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required
Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Azacitidine 100 mg injection, 1 vial

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

- **DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**

  **Authority required (STREAMLINED)**

  6234

  Kaposi sarcoma

  **Clinical criteria:**
  - The condition must be AIDS-related, **AND**
  - Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
  - The condition must include extensive mucocutaneous involvement.

  **Authority required (STREAMLINED)**

  6274

  Kaposi sarcoma

  **Clinical criteria:**
  - The condition must be AIDS-related, **AND**
  - Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
  - The condition must include extensive visceral involvement.

  doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

  5705G

  Max.Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer

  | 4 | 5 | .. | *1059.20 | * Caelyx [JC] | * Liposomal Doxorubicin SUN [RA] |

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

- **RITUXIMAB**

  **Note** Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression
  - Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
  - Bronchial/subglottic obstruction
  - Pulmonary haemorrhage
  - Parenchymal lung disease
  - Sensory neural hearing loss
  - Recurrent sinonasal disease requiring recurrent surgical interventions
  - Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

  **Note** Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;
  - Cyclophosphamide is not recommended due to the need to preserve gonad function;
  - Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
  - Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
  - Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
  - Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

  **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

  Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

  Applications for authority to prescribe should be forwarded to:

  Department of Human Services
  Prior Written Approval of Complex Drugs
  Reply Paid 9826
  HOBART TAS 7001

  **Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

  **Authority required**

  Severe active granulomatosis with polyangiitis (Wegener's granulomatosis)

  Treatment Phase: Induction of remission

  **Clinical criteria:**
  - The treatment must be for the induction of remission, **AND**
  - Patient must not have previously received this drug for this condition; OR
  - Patient must have received this drug for this condition prior to 1 January 2016, **AND**
  - The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission.

The authority application must be made in writing

**Authority required**

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

**Clinical criteria:**
- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition; **OR**
- Patient must have received this drug for this condition prior to 1 January 2016, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

**Authority required**

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

**Clinical criteria:**
- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

**Authority required**

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- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

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**IMMUNOSTIMULANTS**

**FILGRASTIM**

**Authority required (STREAMLINED)**

**6544**

Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, \textbf{AND}  
- Patient must have had a prior episode of febrile neutropenia; OR  
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), \textbf{AND}  
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, \textbf{AND}  
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

\textbf{Authority required (STREAMLINED)}

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, \textbf{AND}  
- Patient must have had a prior episode of febrile neutropenia; OR  
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), \textbf{AND}  
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, \textbf{AND}  
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

\textbf{Authority required (STREAMLINED)}

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving first-line chemotherapy for Hodgkin disease, \textbf{AND}  
- Patient must have had a prior episode of febrile neutropenia; OR  
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), \textbf{AND}  
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, \textbf{AND}  
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

\textbf{Authority required (STREAMLINED)}

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving chemotherapy for myeloma, \textbf{AND}  
- Patient must have had a prior episode of febrile neutropenia, \textbf{AND}  
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, \textbf{AND}  
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

\textbf{Authority required (STREAMLINED)}

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, \textbf{AND}  
- Patient must have had a prior episode of febrile neutropenia; OR  
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), \textbf{AND}  
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, \textbf{AND}  
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

\textbf{Authority required (STREAMLINED)}

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.
• Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required (STREAMLINED)

6523
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required (STREAMLINED)

6534
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required (STREAMLINED)

6535
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authority required (STREAMLINED)

6536
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

Authority required (STREAMLINED)

6493
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

Authority required (STREAMLINED)

6502
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

Authority required (STREAMLINED)

6516
Chemotherapy-induced neutropenia

Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

Authority required (STREAMLINED)

6653
Mobilisation of peripheral blood progenitor cells

Clinical criteria:
• The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

6654
Mobilisation of peripheral blood progenitor cells

Clinical criteria:
• The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

6679
Assisting bone marrow transplantation

Clinical criteria:
• Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

6680
Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:
• The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.
Severe congenital neutropenia

Clinical criteria:
- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, AND
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

6621
Severe chronic neutropenia

Clinical criteria:
- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, AND
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

6640
Chronic cyclical neutropenia

Clinical criteria:
- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, AND
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

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filgrastim 300 microgram/mL injection, 10 x 1 mL vials

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

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LENORASTIM

 Authorities required (STREAMLINED)

6522
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, AND
• Patient must have had a prior episode of febrile neutropenia; OR
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authorities required (STREAMLINED)

6532
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving first-line chemotherapy for Hodgkin disease, AND
• Patient must have had a prior episode of febrile neutropenia; OR
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authorities required (STREAMLINED)

6507
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authorities required (STREAMLINED)

6523
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authorities required (STREAMLINED)

6535
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authorities required (STREAMLINED)

6502
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

Authorities required (STREAMLINED)

6516
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

Authorities required (STREAMLINED)

6644
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

Authorities required (STREAMLINED)

6673
Chemotherapy-induced neutropenia
Clinical criteria:
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin’s lymphoma (intermediate or high grade).

**Authority required (STREAMLINED)**

**6634**  
Chemotherapy-induced neutropenia  
**Clinical criteria:**  
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

**Authority required (STREAMLINED)**

**6682**  
Chemotherapy-induced neutropenia  
**Clinical criteria:**  
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

**Authority required (STREAMLINED)**

**6653**  
Mobilisation of peripheral blood progenitor cells  
**Clinical criteria:**  
• The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**6654**  
Mobilisation of peripheral blood progenitor cells  
**Clinical criteria:**  
• The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**6657**  
Assisting peripheral blood progenitor cell or bone marrow transplantation  
**Clinical criteria:**  
• The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**LENORAGASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10**

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**LENORAGASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10**

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**LIPEGFILGRASTIM**

**Authority required (STREAMLINED)**

**6522**  
Chemotherapy-induced neutropenia  
**Clinical criteria:**  
• Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**  
• Patient must have had a prior episode of febrile neutropenia; OR  
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**  
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**  
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

**6544**  
Chemotherapy-induced neutropenia  
**Clinical criteria:**  
• Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

**Authority required (STREAMLINED)**

**6545**  
Chemotherapy-induced neutropenia  
**Clinical criteria:**  
• Patient must not be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**  
• Patient must have had a prior episode of febrile neutropenia; OR  
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**  
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6532
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6515
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving chemotherapy for myeloma, **AND**
• Patient must have had a prior episode of febrile neutropenia, **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6492
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVA or IVB squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6507
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

6533
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

6523
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

6534
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

6535
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

6536
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

Authority required (STREAMLINED)

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

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**PEGFILGRASTIM**

Authority required (STREAMLINED)

Clinical criteria:
- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

Authority required (STREAMLINED)

Clinical criteria:
- Patient must be receiving chemotherapy for breast cancer, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

Clinical criteria:
- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

Clinical criteria:
- Patient must be receiving first-line chemotherapy for Hodgkin disease, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

Clinical criteria:
- Patient must be receiving chemotherapy for myeloma, AND
- Patient must have had a prior episode of febrile neutropenia, AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.
• Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
• The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
• Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6507
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

6533
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

**Authority required (STREAMLINED)**

6523
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required (STREAMLINED)**

6534
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

**Authority required (STREAMLINED)**

6535
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required (STREAMLINED)**

6536
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

**Authority required (STREAMLINED)**

6493
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

**Authority required (STREAMLINED)**

6502
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required (STREAMLINED)**

6516
Chemotherapy-induced neutropenia

**Clinical criteria:**

• Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

**pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

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**Interferons**
### INTERFERON ALFA-2A

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

**5042**

**Chronic Myeloid Leukaemia (CML)**

**Clinical criteria:**
- The condition must be Philadelphia chromosome positive.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

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**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

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### INTERFERON ALFA-2B

**Caution** Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

**5042**

**Chronic Myeloid Leukaemia (CML)**

**Clinical criteria:**
- The condition must be Philadelphia chromosome positive.

**Authority required (STREAMLINED)**

**4974**

**Malignant melanoma**

**Clinical criteria:**
- The treatment must be as adjunctive therapy to current standard care, **AND**
- Patient must have undergone surgery, **AND**
- The condition must include nodal involvement.

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

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**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

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**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

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**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

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**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

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**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

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</table>

### INTERFERON GAMMA-1B

**Authority required (STREAMLINED)**

**6222**

**Chronic granulomatous disease**

**Clinical criteria:**
- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.
interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>Imukin [BY]</td>
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PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

**Authority required (STREAMLINDED)**

5004

**Chronic hepatitis C infection**

**Treatment criteria:**

- Must be treated in an accredited treatment centre.
- Population criteria:
  - Patient must be aged 18 years or older, **AND**
  - Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.
- Clinical criteria:
  - Patient must have compensated liver disease, **AND**
  - Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
  - Patient must have a contraindication to ribavirin, **AND**
  - The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
  - The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>Pegasys [RO]</td>
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peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

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<th>Brand Name and Manufacturer</th>
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<td>Pegasys [RO]</td>
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PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

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<th>Brand Name and Manufacturer</th>
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<td>Pegasys [RO]</td>
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**Other immunostimulants**

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required (STREAMLINDED)**

4549

Mobilisation of haematopoietic stem cells

**Clinical criteria:**
• The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), AND
• Patient must have lymphoma; OR
• Patient must have multiple myeloma, AND
• Patient must require autologous stem cell transplantation, AND
• Patient must have failed previous stem cell collection; OR
• Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
• Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

plerixafor 24 mg/1.2 mL subcutaneous infusion injection, 1.2 mL vial

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<tr>
<th>Max.Qty.Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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**IMMUNOSUPPRESSANTS**

**Selective immunosuppressants**

**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

• Patient must have severe active rheumatoid arthritis, AND
• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
• Patient must have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
• Patient must not receive more than 16 weeks of treatment under this restriction, AND
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

• Patient must be aged 18 years or older.

**Treatment criteria:**

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-
subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when...
commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
• Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
• Patient must not receive more than 16 weeks of treatment under this restriction, AND
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
• Patient must be aged 18 years or older.
• For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
• an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HSD (Public)

Note: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial abatacept, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-α antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.
Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Clinical criteria:
Highly Specialised Drugs Program (Public Hospital)  1101

• Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
• Patient must have demonstrated an adequate response to treatment with this drug, AND
• Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
• Patient must be aged 18 years or older.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Note: **TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

   (a) Initial treatment.

   Applications for initial treatment should be made where:

   (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

   (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

   (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

   (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

   Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

   Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

   A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

   Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

   For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   Abatacept patients:

   Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

   Abatacept patients:

   A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

   (b) Continuing treatment.

   Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

   Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients:

   A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most
recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### abatacept 250 mg injection, 1 vial

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<th>Max Qty</th>
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**ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

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<tr>
<th>6847</th>
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<td>Treatment Phase: Continuing treatment</td>
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</table>

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

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<th>alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial</th>
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**ALEMTUZUMAB**

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

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<td>Treatment Phase: Initial treatment</td>
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**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

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<th>alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial</th>
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**ECULIZUMAB**

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**
Atypical haemolytic uraemic syndrome (aHUS)
Treatment Phase: Initial treatment - Balance of Supply

**Treatment criteria:**
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

**Clinical criteria:**
- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, AND
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, AND
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

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**ECULIZUMAB**

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;
- In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

1. a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:
   - (i) presence of schistocytes on blood film;
   - (ii) low or absent haptoglobin;
   - (iii) lactate dehydrogenase (LDH) above normal range;

OR

2. in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; **AND**

3. (i) a serum creatinine (sCr) of greater than the age-appropriate ULN in paediatric patients; or
   - (ii) a sCr of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   - (iii) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber’s cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A detailed cover letter from the prescriber; and
5. A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
6. A measurement of body weight at the time of application; and
7. The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
8. In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-** balance of supply; and
Note
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI).
Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note
For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Note
Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note
Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;
- In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note
The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note
The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.
Written applications for authority to prescribe must be submitted to the Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:
- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, AND
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
- Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
- An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
- An eGFR within +/- 25% from baseline; or
- An avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and
(3) A detailed cover letter from the prescriber; and
(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
(5) A measurement of body weight at the time of application; and
(6) An identified genetic mutation, if applicable; and
(7) A family history of aHUS, if applicable; and
(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
(10) An inclusion of the individual consequences of recurrent disease, if applicable; and
(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Eculizumab 300 mg/30 mL injection, 30 mL vial**

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**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

a) Active malignancy;
b) Active HIV infection;
c) Hematopoietic stem cell transplants;
d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
f) Active autoimmune diseases;
In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;
b) Results of testing for genetic mutations (if available);
c) Family history of aHUS, especially in first-degree relatives;
d) Patient’s prior history of episodes of active and progressing TMA caused by aHUS;
e) Exclusion of alternative causes of TMA;
f) History of renal or other organ transplant (if any);
g) Any other matters considered relevant by the prescriber.
In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber’s interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

### Authority required

**Atypical haemolytic uraemic syndrome (aHUS)**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, AND
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
2. One of the following:
   - An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   - an eGFR within +/- 25% from baseline; or
   - an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:
1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
3. A detailed cover letter from the prescriber; and
4. A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
5. A measurement of body weight at the time of application; and
6. An identified genetic mutation, if applicable; and
7. A family history of aHUS, if applicable; and
8. A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
9. A history of kidney transplant if applicable (especially if required due to aHUS); and
10. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH; and an eGFR level of no more than 1 week old at the time of application; and
11. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
12. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
13. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

### Authority required

**Atypical haemolytic uraemic syndrome (aHUS)**

**Treatment Phase: Extended Continuing treatment**

**Clinical criteria:**
- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, AND
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, AND
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
Note

All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- Evidence of a mutation known to confer a high risk of aHUS recurrence;
- Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- Past family history of aHUS recurrence, especially in first-degree relatives;
- Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, AND
• Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
• Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; **AND** (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count < 150 x 10^9/L); **OR** (iii) TMA-related organ impairment including on recent biopsy, **AND**
• Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
• Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
2. One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   b) an eGFR within +/- 25% from baseline; or
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
1. dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
2. on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:
1. A completed authority prescription form(s); and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A detailed cover letter from the prescriber; and
5. A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
6. A measurement of body weight at the time of application, and
7. An identified genetic mutation, if applicable; and
8. A family history of aHUS if applicable; and
9. A history of multiple episodes of aHUS following the treatment break, if applicable; and
10. A history of kidney transplant if applicable (especially if required due to aHUS); and
11. An inclusion of the individual consequences of recurrent disease; and
12. A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
13. Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
14. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
15. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

**Authority required**
- Atypical haemolytic uremic syndrome (aHUS)

**Treatment Phase: Continuing recommencement of treatment**

**Clinical criteria:**
• Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
• Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
• Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
• Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
• Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.
A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

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### EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**5795** Management of renal allograft rejection

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**5554** Management of cardiac allograft rejection

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND

- The treatment must be under the supervision and direction of a transplant unit.

**everolimus 750 microgram tablet, 60**

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**everolimus 1 mg tablet, 60**

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everolimus 500 microgram tablet, 60

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everolimus 250 microgram tablet, 60

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\section*{Mycophenolate}

\textbf{Caution} Careful monitoring of patients is mandatory.

\textbf{Authority required (STREAMLINED)}

\textbf{5795}

Management of renal allograft rejection

\textbf{Treatment Phase:} Management (initiation, stabilisation and review of therapy)

\textbf{Clinical criteria:}

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, \textbf{AND}
- The treatment must be under the supervision and direction of a transplant unit.

\textbf{Authority required (STREAMLINED)}

\textbf{5554}

Management of cardiac allograft rejection

\textbf{Treatment Phase:} Management (initiation, stabilisation and review of therapy)

\textbf{Clinical criteria:}

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, \textbf{AND}
- The treatment must be under the supervision and direction of a transplant unit.

\textbf{Mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL}

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\textbf{Mycophenolate mofetil 500 mg tablet, 50}

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\textbf{Mycophenolate}

\textbf{Caution} Careful monitoring of patients is mandatory.

\textbf{Note} Management includes initiation, stabilisation and review of therapy as required.

\textbf{Authority required (STREAMLINED)}

\textbf{4084}

Prophylaxis of renal allograft rejection

\textbf{Treatment Phase:} Management

\textbf{Clinical criteria:}

- The treatment must be under the supervision and direction of a transplant unit.

\textbf{Authority required (STREAMLINED)}

\textbf{4095}

WHO Class III, IV or V lupus nephritis

\textbf{Treatment Phase:} Management

\textbf{Clinical criteria:}

- The condition must be proven by biopsy.

\textbf{Treatment criteria:}

- Must be treated by a nephrologist or in consultation with a nephrologist.
- The name of the consulting nephrologist must be included in the patient medical records.

\textbf{Mycophenolate 180 mg enteric tablet, 120}

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\textbf{Mycophenolate 360 mg enteric tablet, 120}

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\textbf{Mycophenolate}

\textbf{Caution} Careful monitoring of patients is mandatory.

\textbf{Note} For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

**mycophenolate mofetil 250 mg capsule, 100**

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<td>* Mycophenolate Sandoz [SZ]</td>
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**mycophenolate Capsule 250 mg, 50**

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**NATALIZUMAB**

Caution  Progressive multifocal leukoencephalopathy has been reported with this drug.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

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**SIROLIMUS**

Caution  Careful monitoring of patients is mandatory.

**sirolimus 1 mg tablet, 100**

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### VEDOLIZUMAB

**Note Special Pricing Arrangements apply.**

**Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

1. How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016.
   (a) Initial treatment. Applications for initial treatment should be made where:
      (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
      (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
      (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).
   Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.
   A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alpha antagonist. For second and subsequent courses of PBS-subsidised TNF-alpha antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
   (b) Continuing treatment.
   Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
   (2) Swapping therapy.
   Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

### Drugs Table

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Treatment Phase: Initial treatment (new patient – Initial 1)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**
- Patient must be aged 18 years or older.

Applications for authorisation of initial treatment must be in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Collitis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.
Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
• Patient must have previously been issued with an authority prescription for this drug for this condition, AND
• Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND
• Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:
• Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, AND
• Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, AND
• Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:
• Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.
At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose. Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services. 

**Note**

No applications for increased repeats will be authorised. 

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). 

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au 

Applications for authority to prescribe should be forwarded to: 
Department of Human Services 
Complex Drugs 
Reply Paid 9826 
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis 
Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR 
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR 
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR 
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR 
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND** 
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction), **AND** 
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be 18 years or older. Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Moderate to severe ulcerative colitis 
Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, **AND** 
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR 
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR 
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic baseline assessment is not available, **AND** 
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND** 
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be 18 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR 
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR 
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include: 

(a) a completed authority prescription form; and 

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: 
(i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and 
(ii) the date of commencement of this drug; and 
(iii) the signed patient acknowledgement.
 vedolizumab 300 mg injection, 1 vial

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may swap the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a
'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR
- Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
- Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR
- Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
- (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
- (iv) the date of the most recent clinical assessment; and
- (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment
If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Note: This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment; and
(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.
This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note
It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

**Treatment Phase: Initial PBS-subsidised treatment (Grandfather)**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, AND
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015.

**Population criteria:**
- Patient must be aged 18 years or older.

**Clinical criteria:**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, AND
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, AND
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment; and
  - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Authority required**

Severe Crohn disease

**Treatment Phase: Balance of supply**

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), **AND**
- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Severe Crohn disease

**Treatment Phase: Continuing treatment**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
- (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
- (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- (iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.
**ADALIMUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Tumor necrosis factor alpha (TNF-) inhibitors

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.
- For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
- Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.
- Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.
- If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
- If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.
- The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
  - an active joint count of at least 20 active (swollen and tender) joints; OR
  - at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- The joint count assessment must be performed preferably whilst on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- The authority application must be made in writing and must include:
  - (1) a completed authority prescription form; and
  - (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
  - (3) an acknowledgement signed by a parent or authorised guardian.
- At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.
- If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the
baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they...
may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.
**Authority required**
Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have demonstrated an adequate response to treatment with adalimumab, AND
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has had a break in bDMARD treatment of more than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a new treatment cycle.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restrictions, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline...
measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD
therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete
remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the
Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment – balance of supply
Treatment criteria:
• Must be treated by a rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Clinical criteria:
• Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24
weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone
by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to
Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be
forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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ETANERCEPT

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12
months)
Treatment criteria:
• Must be treated by a paediatric rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Clinical criteria:
• Patient must have severe active juvenile idiopathic arthritis, AND
• Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug
(bDMARD) for this condition; OR
• Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition
in the previous 12 months, AND
• Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
• Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment
regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in
combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at
least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD),
alone or in combination with corticosteroids, for a minimum of 3 months, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.
Population criteria:
• Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient
acknowledgement.
For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab,
etanercept or tocilizumab.
Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to
manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of
methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

 Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or severe sepsis.

 If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

 If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

 The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

 The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

 The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

 At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

 If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

 **Note**

 Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

 **Note**

 Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

 Applications for authority to prescribe should be forwarded to:

 Department of Human Services
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

 **Note**

 **TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

 A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

 From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

 Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

 A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

 A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

 A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

 There is no limit to the number of treatment cycles a patient may undertake.

 (1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

 (a) Initial treatment.

 Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or repeating implies for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)**

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.
Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4
weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase: Initial treatment** - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase: Continuing treatment**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

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### Authority required

**Severe active juvenile idiopathic arthritis**

**Treatment Phase:** Continuing treatment – balance of supply

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

### ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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### ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

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INFLIXIMAB

Note: No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4524
Acute severe ulcerative colitis

Treatment criteria:
• Must be treated by a gastroenterologist; OR
• Must be treated by a consultant physician (internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology).

Clinical criteria:
• Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, AND
• Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
• Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, AND
• Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:
• Patient must be 6 years of age or older.
For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:
(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L
(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.
For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.
At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.
Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient’s medical records.
Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

infliximab 100 mg injection, 1 vial

10067W

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INFLIXIMAB

Note: Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note: TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required

Initial 1
Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Authority required

Initial 2
Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The authority application must be made in writing

Authority required

Initial 3

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has an externally draining enterocutaneous or rectovaginal fistula; and
(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.
An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The authority application must be made in writing

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

The authority application must be made in writing

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authorised applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

The authority application must be made in writing

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### INFliximab

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is
reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND
- Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

Population criteria:
- Patient must be aged 6 to 17 years inclusive.
- Applications for authorisation of initial treatment must be in writing and must include:
  (a) a completed authority prescription forms; and
  (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
    (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
    (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and
    (iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe Crohn disease
Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Clinical criteria:
- Patient must have a documented history of moderate to severe Crohn disease, AND
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.
**Population criteria:**
- Patient must be aged 6 to 17 years inclusive.
To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.
Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.
Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed paediatric Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.
A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.
If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.
A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.
This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

**Clinical criteria:**
- Patient must have a documented history of moderate to severe Crohn disease.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

**Population criteria:**
- Patient must be aged 6 to 17 years inclusive.
Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.
The PCDAI assessment must be no more than 1 month old at the time of application.
If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.
The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response. A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the ‘Balance of Supply’ treatment phase PBS restriction.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Moderate to severe Crohn disease
Treatment Phase: Balance of supply for a paediatric patient

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, AND
- The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

**Note:** Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

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**INFLIXIMAB**

**Note:** TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab,or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to
commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle. A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab. From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For second and subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy. A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
Note

No applications for increased maximum quantities will be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

• Must be treated by a gastroenterologist (code 87): OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]: OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

• Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
• Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; **OR**
• Patient must have achieved a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, **AND**
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; **OR**
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; **OR**
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug.

Population criteria:

• Patient must be aged 18 years or older.

Clinical criteria:

• Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; **OR**
• Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, **AND**
• Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; **OR**
• Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; **OR**
• Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated 
erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 
15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: 
demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric 
lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as requiring surgery or total parenteral 
nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the 
patient's condition if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iv) details of this toxicity must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated phase in the relevant treatment phase are requested at the time of the application, 
authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may 
be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply 
restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the 
relevant treatment phase.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose 
(6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine response for ongoing PBS-subsidised treatment, as outlined in the 
restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved 
Product Information, please provide details at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for 
continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion 
must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-
subsidiised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated phase in the relevant treatment phase are requested at the time of the application, 
authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may 
be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply 
restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the 
relevant treatment phase.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose 
(6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine response for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these 
timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-
subsidiised treatment with this drug.

Authority required
Severe Crohn disease
Treatment Phase: Change or Re-commencement of treatment (initial 2)
Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].
Clinical criteria:
• Patient must have a documented history of severe Crohn disease, AND
• Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in 
this treatment cycle, AND
• Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.
Population criteria:
• Patient must be aged 18 years or older.
Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the 
patient’s condition, if relevant; or
(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with 
short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment; and
(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

### INFILXIMAB

**Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be made to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For sequential and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to

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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**
completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a
course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the
date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these
timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate
infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to
the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and
immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving
therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they
cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same
treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is
important that they are assessed for response to every course of treatment approved, within the timeframes specified in the
relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab,
vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for
the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the
baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for
infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than
when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services
will assess response according to these revised baseline measurements. To ensure consistency in determining response,
the same indices of disease severity used to establish baseline at the commencement of treatment with each initial
treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial an alternate treatment within the same treatment cycle or subsequent course of treatment, will break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of
disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for
induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum
of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed
thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment
withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016
and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’
treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will
be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for
treatment will be assessed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will
only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that
apply to a continuing patient.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients
with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.
Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to
infliximab, vedolizumab or adalimumab. A patient is eligible for PBS-subsidised treatments only if they have received treatment
with 1 of the 2 TNF-alfa antagonists at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is
PBS-subsidised for acute severe disease. From 1 June 2017, under the PBS, all will be able to commence a treatment cycle
where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping
to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a
patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to
therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 June 2017 is considered to be in
their first cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the
same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to
treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break
in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is
measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to
the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who
has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5
years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3
trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a
new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.(1) How to
 prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 June 2017.(a) Initial treatment. Applications for initial treatment
should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a TNF-alfa antagonist and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iii) a patient wishes to commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 3). Treatment authorisations under Initial 1 and Initial 2 will be
limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1
June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of
12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for
infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the
date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient commencing their current course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate drug response. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping treatment. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate agent at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PUCAI score. However, prescribers may provide new baseline measurements any time other than when an initial treatment cycle is concluded, and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for 3 consecutive months or have intolerance necessitating permanent treatment withdrawal to these agents immediately prior to the time the PUCAI score is measured. (5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab. A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 June 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiouprine agent, **AND**
Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating
Department of Human Services
HOBART TAS 7001
Reply Paid 9826
Complex Drugs

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

• Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
• Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency
subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
• Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17
years; OR
• Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in
the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial
Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17
years).

Population criteria:
• Patient must be 6 years of age or older.
Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation
sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement or guardian acknowledgement.
A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg
body weight per dose to be administrated at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who
have received prior treatment for an acute severe episode, will be authorised.
All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following
cessation of the most recent prior conventional treatment.
The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no
more than 1 month old at the time of application.
Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be
demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than
1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12
weeks of receiving this drug for acute severe ulcerative colitis.
Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a
Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for
ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than
1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will
not be eligible to receive further PBS-subsidised treatment with this drug.
A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial
course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6
weeks following the third dose) so that there is adequate time for a response to be demonstrated.
The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating
that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the
predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing
treatment.
If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product
Information, details must be provided at the time of application.
If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent
treatment withdrawal, details of this toxicity must be provided at the time of application.
Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note

• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [interna1 medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
• Must be treated by a paediatrician; OR
• Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:
• Patient must have previously been issued with an authority prescription for this drug for this condition, AND
• Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score
less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
• Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative
Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.
Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

The authority application must be made in writing

Up to a maximum of 2 repeats will be authorised.

**Note** No applications for increased repeats will be authorised.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Moderate to severe ulcerative colitis**

**Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with adalimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with infliximab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy];

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

**Note** No applications for increased repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Moderate to severe ulcerative colitis**

**Treatment Phase: Balance of supply**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a specialist paediatric gastroenterologist.
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician; OR
Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommeniment of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

Population criteria:
- Patient must be 6 years of age or older.
Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

### INFLIXIMAB

**Authority required**
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, AND
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.
The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.
Both ESR and CRP measures should be provided with the initial application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

• Patient must have a documented history of active ankylosing spondylitis, AND
• Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND
• Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
• Patient must be eligible to receive further bDMARD therapy.

Population criteria:

• Patient must be an adult.

Treatment criteria:

• Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such
therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent
(Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with
that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5
years).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks
of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the
date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient
will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in
the month prior to completing their current course of treatment and that an application is posted to the Department of Human
Services no later than 2 weeks prior to the patient completing their current course of treatment.
(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab forankylosing spondylitis prior to 1 October 2016, applications
for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial
3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been
treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of
treatment for all agents. Approval will be based on the criteria included in the relevant restriction
(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24
weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The
patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing
they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure
uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD
within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the
erthrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and
exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing)
with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to
respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is
important that they are assessed for response to every course of treatment approved, within the timeframes specified in the
relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the
approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the
baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is
submitted within a treatment cycle and the Department of Human Services will assess response according to these revised
baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID
therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment
applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be
provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy
of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have
received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to
the time the BASDAI, ESR and/or CRP levels are measured.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) –
balance of supply
Clinical criteria:
• Patient must have active, or a documented history of active, ankylosing spondylitis, AND
• Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, **AND**
• The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Population criteria:**
• Patient must be an adult.

**Treatment criteria:**
• Must be treated by a rheumatologist.

**Note**
Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Ankylosing spondylitis
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have a documented history of active ankylosing spondylitis, **AND**
• Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
• Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**
• Patient must be an adult.

**Treatment criteria:**
• Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.
Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Grandfather patients - secukinumab only.
For patients who commenced treatment with secukinumab for ankylosing spondylitis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(c) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI); or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Highly Specialised Drugs Program (Public Hospital) 1161

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
• Patient must have a documented history of active ankylosing spondylitis, AND
• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial
5753T

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\textbf{INFLIXIMAB}

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have severe active rheumatoid arthritis, AND
• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
• Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
• Patient must not receive more than 22 weeks of treatment under this restriction, AND
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
• Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.
If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDS) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy.
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised bDMARD treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify with Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restrictions.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the
C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.
Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the...
dosing regimen). 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be consistent with the relevant indication. Accordingly, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with infliximab, **AND**
- Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- **AND** either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

A patient’s request concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010:

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

#### infliximab 100 mg injection, 1 vial

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**INFLIXIMAB**

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**
- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; **OR**
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment
course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment may have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5
years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. **Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised biological therapy below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below]. The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

1. Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

**Treatment Phase: Continuing treatment - balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

INFLIXIMAB

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are deemed to have commenced a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is, they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent therapy in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised treatment of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

1. Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients who wish to recommence treatment following a break of 5 years or more and commence a new treatment cycle (Initial 1); or

(iii) patients who have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '4) Switching therapy' below]; or

(iv) patients who wish to recommence treatment following a break of less than 5 years in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment of adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of treatment of infliximab and 28 weeks of treatment of ustekinumab.

Grandfather patients (ixekizumab only).
Applications for patients who commenced treatment with ixekizumab for chronic plaque psoriasis prior to 1 February 2017 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

• Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND
• Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR
• Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND
• Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND
• Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
  For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
  Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.
  Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
  (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month following the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
  For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
  The authority application must be made in writing and must include:
  (a) a completed authority prescription form; and
A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy (dosage (where applicable), date of commencement and duration of therapy); and
(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note: Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

Note: A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note: It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.
- For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

**Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** If patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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### Authority required

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years) restriction to complete 22 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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### Authority required

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have a documented history of severe chronic plaque psoriasis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.
The most recent PASI assessment must be no more than 1 month old at the time of application.
Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

**Authority required**
Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Face, hand, foot

**Clinical criteria:**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.
For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, ixekizumab, secukinumab or ustekinumab.
An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.
Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.
The most recent PASI assessment must be no more than 1 month old at the time of application.
Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.
The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

**Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**
  • Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
  • Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
  • The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
  • The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**
  • Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**interleukin inhibitors**

### ANAKINRA

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required [STREAMLINED]**
5450
Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**
  • Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
  • Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

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### TOCILIZUMAB

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Treatment criteria:**
  • Must be treated by a paediatric rheumatologist; OR
  • Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
  • Patient must have severe active juvenile idiopathic arthritis, **AND**
  • Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
  • Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
  • Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
  • Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
  • Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.
  For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3. an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time. From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD therapy 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment. Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
   (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
   (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission. Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatement Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.
The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

From 1 April 2014, a patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks after the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a rheumatology treatment centre.
Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such...
therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:
- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
### TOCILIZUMAB

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if etanercept is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance and dose for each DMARD which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance and dose for each DMARD which must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.
- For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
- If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
- The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.
- The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.
- If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
The count and ESR and/or CRP must be determined at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) substituting a patient from the requirement to undertake a minimum 3-month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6-month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6-month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks...
of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 2 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Treatment criteria:

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

• Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
• Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
• Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

• Patient must be aged 18 years or older.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (or more often with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  - (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  - (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note**
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4...
weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
- Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- Patient must be aged 18 years or older.
- For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or

- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy (Initial 2) [further details are under ‘Swapping therapy’ below]; or

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
• TOCILIZUMAB

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have severe active rheumatoid arthritis, AND
• Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
• Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
• Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.
If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-
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The Highly Specialised Drugs Program (Public Hospital) is designed to provide subsidised therapy with highly specialised agents. Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy for infliximab, certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

- Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
- Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

- A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
- Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

- Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

<table>
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<th>Authority required</th>
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<td>Severe active rheumatoid arthritis</td>
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Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tocافتینین.

The authority application must be made in writing and must include:
- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term
bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARD for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib. 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient...
will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Treatment criteria:

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

• Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
• Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
• Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
• Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is
sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-α/α antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is...
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9657G

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**TOCILIZUMAB**

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from...
the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or

(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course. For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.

(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Systemic juvenile idiopathic arthritis

**Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)**

**Clinical criteria:**

- Patient must have been diagnosed with systemic juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; **OR**
• Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

• Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

• Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

• Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, AND

• Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

• Patient must be under 18 years of age.

**Treatment criteria:**

• Must be treated by a rheumatologist; OR

• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note**

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

**Note**

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.
Note
Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:
• Patient must have a documented history of systemic juvenile idiopathic arthritis, AND
• Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND
• Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:
(a) in a patient with polyarticular course disease:
   (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
   (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
       - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
       - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:
   (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
   (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
   (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis

Complex Drugs
Department of Human Services
HOBART TAS 7001

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis
Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month’s supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

• Must be treated by a rheumatologist; OR

• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

• Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

• Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, AND

• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

• Must be treated by a rheumatologist; OR

• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

Clinical criteria:

• Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR

• Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, AND

• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

• Must be treated by a rheumatologist; OR

• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Note An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Systemic juvenile idiopathic arthritis
Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**
- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

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**USTEKINUMAB**

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.
A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to be in their first cycle as of 1 September 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial 1 - new patients); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - Change or Re-commencement).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks for vedolizumab patient and 16 weeks for ustekinumab. From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.

For all subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy. A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap adalimumab, infliximab, vedolizumab or ustekinumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for
adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured. Patients ‘grandfathered’ onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

(6) Patients ‘grandfathered’ onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for continuing treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.
• Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iv) the date of the most recent clinical assessment; and
(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note: Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Authority required**

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

**Treatment criteria:**
- Must be treated by a gastroenterologist [code 87]; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology [code 81]]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology [code 82]].

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

**Population criteria:**
- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:
(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition, if relevant; and
(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment; and
(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.
Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

### ustekinumab 130 mg/26 mL injection, 26 mL vial

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**Calcineurin inhibitors**

#### CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**6628**

Management of transplant rejection

**Clinical criteria:**
- The treatment must be used by organ or tissue transplant recipients.

**cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

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#### CYCLOSPORIN

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**6643**

Management of transplant rejection

**Treatment Phase: Management (initiation, stabilisation and review of therapy)**

**Clinical criteria:**
- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**6660**

Severe atopic dermatitis

**Treatment Phase: Management (initiation, stabilisation and review of therapy)**

**Clinical criteria:**
- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologists.

**Clinical criteria:**
- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies.

**Authority required (STREAMLINED)**

**6676**

Severe psoriasis

**Treatment Phase: Management (initiation, stabilisation and review of therapy)**

**Clinical criteria:**
- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**
- Must be treated by a dermatologist.

**Authority required (STREAMLINED)**

**6631**

Nephrotic syndrome
Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Treatment criteria:**
- Must be treated by a nephrologist.

**Authority required (STREAMLINED)**

**6638**
Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**
- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

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**TACROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**5569**
Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**
- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

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## TACROLIMUS

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### tacrolimus 750 microgram capsule, 100

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### Other Immunosuppressants

#### LENALIDOMIDE

**Note** Special Pricing Arrangements apply.

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias. Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and
(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
(d) a copy of the full blood examination report; and
(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
(g) a signed patient acknowledgement form.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, AND
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, AND
- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.
The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.
The following evidence of response must be provided at each application:
(i) a haemoglobin level taken within the last 4 weeks; and
(ii) the date of the last transfusion; and
(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note
Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 5 mg capsule, 21

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Brand Name and Manufacturer
Revlimid [CJ]

lenalidomide 10 mg capsule, 21

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Brand Name and Manufacturer
Revlimid [CJ]

• LENALIDOMIDE

Note
Special Pricing Arrangements apply.

Authority required
Multiple myeloma
Treatment Phase: Initial PBS-subsidised treatment
Clinical criteria:
- The condition must be confirmed by a histological diagnosis, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, AND
- Patient must have progressive disease after at least one prior therapy, AND
- Patient must have undergone or be ineligible for a primary stem cell transplant, AND
- Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, AND
- Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

- Patient must have previously received an authority prescription for lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**
Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Special Pricing Arrangements apply.

**Authority required**
Multiple myeloma
Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and
3. a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:
- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** Patient must be registered in the i-access risk management program.

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**Authority required**
Multiple myeloma
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving PBS subsidised bortezomib for this condition, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Lenalidomide 5 mg capsule, 21**

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**Pomalidomide**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Special Pricing Arrangements apply.

**Authority required**
Multiple myeloma
Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
• Patient must have experienced treatment failure with bortezomib, AND
• Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Multiple myeloma
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously been issued with an authority prescription for this drug, AND
• Patient must not have progressive disease, AND
• The treatment must be in combination with dexamethasone, AND
• Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

pomalidomide 3 mg capsule, 21

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**RITUXIMAB**

*Note*  
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the Janus kinase (JAK) inhibitor (tofacitinib), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tacrolimus).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that bDMARD (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the commencement of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Abatacept patients:
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated or intolerant including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

For the purposes of this restriction "TNFα" antagonist means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and rituximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for period of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
- Patient must be aged 18 years or older.
- For the purposes of this restriction "TNFα" antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- either:
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note: The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
• Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND
• Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
• Patient must not receive more than 2 infusions of rituximab under this restriction, AND
• The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
• Patient must be aged 18 years or older.
• For the purposes of this restriction "TNF" alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.
• For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:
• an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with this drug, AND
Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-
rheumatic drug (bDMARD) treatment for this condition, AND
Patient must not receive more than 2 infusions of rituximab under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:
- Patient must be aged 18 years or older.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:
(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

rituximab 500 mg/50 mL injection, 50 mL vial

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THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required (STREAMLINED)

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MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

Other centrally acting agents

BACLOFEN

Authority required (STREAMLINED)

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Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to spinal cord disease.

**BACLOFEN**

Note: Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity of cerebral origin.

**Authority required (STREAMLINED)**

Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

Severe chronic spasticity

Clinical criteria:
- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

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baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

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baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

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DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

IBANDRONATE

**Authority required (STREAMLINED)**

5291

Bone metastases

Clinical criteria:
- The condition must be due to breast cancer.

**ibandronate 6 mg/6 mL injection, 6 mL vial**

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PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

4433

Hypercalcaemia of malignancy

Clinical criteria:
- Patient must have a malignancy refractory to anti-neoplastic therapy.

**pamidronate disodium 15 mg/5 mL injection, 5 mL vial**

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**pamidronate disodium 30 mg/10 mL injection, 10 mL vial**

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**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

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PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

4433

Hypercalcaemia of malignancy

**Authority required (STREAMLINED)**

5218

Multiple myeloma

**Authority required (STREAMLINED)**

5291

Bone metastases

Clinical criteria:
- The condition must be due to breast cancer.

**pamidronate disodium 90 mg/10 mL injection, 10 mL vial**

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ZOLEDRONIC ACID

**Note** Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

5735

Multiple myeloma

**Authority required (STREAMLINED)**

5605

Bone metastases

Clinical criteria:
- The condition must be due to breast cancer.
5703
Bone metastases
Clinical criteria:
• The condition must be due to castration-resistant prostate cancer.
Authority required (STREAMLINED)
5704
Hypercalcaemia of malignancy
Clinical criteria:
• Patient must have a malignancy refractory to anti-neoplastic therapy.

**Zoledronic acid 4 mg/100 mL injection, 100 mL vial**

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**Zoledronic acid 4 mg/5 mL injection, 5 mL vial**

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<td>* Zometa [NV]</td>
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**Zoledronic acid 4 mg/100 mL injection, 100 mL bag**

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### NERVOUS SYSTEM

#### ANTI-PARKINSON DRUGS

**DOPAMINERGIC AGENTS**

Dopa and dopa derivatives

### LEVODOPA + CARBIDOPA ANHYDROUS

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required (STREAMLINED)**

6863
Advanced Parkinson disease
Clinical criteria:
• Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
• The treatment must be commenced in a hospital-based movement disorder clinic.

**Levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

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**Dopamine agonists**

**APOMORPHINE**

**Authority required (STREAMLINED)**

6813
Parkinson disease
Clinical criteria:
• Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**Apomorphine hydrochloride 100 mg/20 mL injection, 5 x 20 mL vials**

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**APOMORPHINE**

**Authority required (STREAMLINED)**

4833
Parkinson disease
Clinical criteria:
• Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

**Apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

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RESPIRATORY SYSTEM

apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules
10227G

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apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
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apomorphine hydrochloride 50 mg/10 mL injection, 5 x 10 mL syringes
10950H

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PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

Authority required (STREAMLINED)

5015 Schizophrenia
Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:
• Patient must be non-responsive to other neuroleptic agents; OR
• Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 200 mg tablet, 100
5627E

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clozapine 25 mg tablet, 100
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clozapine 100 mg tablet, 100
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clozapine 50 mg/mL oral liquid, 100 mL
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RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

MEPOLIZUMAB

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.
Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a ‘mepolizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:
Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See “Re-commencement of treatment after a 6 month break in PBS-subsidised therapy” below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe eosinophilic asthma

HSD (Public)
RESPIRATORY SYSTEM

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
- Patient must be under the care of the same physician for at least 12 months, AND
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND
- Patient must have a duration of asthma of at least 1 year, AND
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, AND
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, AND
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, AND
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:
- Patient must be aged 12 years or older.

Optimised asthma therapy includes:
- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
  - (iii) the signed patient or parent/guardian acknowledgement; and
  - (c) a copy of the eosinophil pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms to establish baseline score and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated.

Mepolizumab 100 mg injection, 1 vial

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Mepolizumab

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.
Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a ‘mepolizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or, if eligible, an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:
Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:
For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required
Uncontrolled severe eosinophilic asthma
Treatment Phase: Continuing treatment
Treatment criteria:

• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

• Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, AND

• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

• Patient must be aged 12 years or older.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of treatment. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30 weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.
RESPIRATORY SYSTEM

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Uncontrolled severe eosinophilic asthma
Treatment Phase: Initial treatment - grandfather patients

Clinical criteria:

• Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, AND

• Patient must be receiving treatment with this drug for this condition at the time of application, AND

• Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND

• Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, AND

• Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, AND

• Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND

• Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, AND

• Patient must have demonstrated an adequate response to treatment with mepolizumab, AND

• The treatment must not be used in combination with omalizumab.

Population criteria:

• Patient must be aged 12 years or older.

Treatment criteria:

• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient’s records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma
Control Questionnaire (ACQ-5) score of at least 0.5; and/or (ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient’s response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction only if:

- A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:
(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and
(iii) the signed patient or parent/guardian acknowledgement; and
(c) a copy of the pre-mepolizumab eosinophil pathology report.

Note: The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note: It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Note: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

mepolizumab 100 mg injection, 1 vial

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OMALIZUMAB

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic spontaneous urticaria
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).
**Clinical criteria:**
- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), AND
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, AND
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, AND
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:
1) a H2 receptor antagonist (150 mg twice per day); or
2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
(i) demonstration of failure to achieve an adequate response to standard therapy; and
(ii) drug names and doses of standard therapies that the patient has failed; and
(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Omalizumab 150 mg/mL injection, 1 mL syringe**

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**OMALIZUMAB**

**Authority required**
Severe chronic spontaneous urticaria
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Severe chronic spontaneous urticaria
Treatment Phase: Grandfathering treatment

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017, AND
- Patient must have documented history of itch and hives that persisted on a daily basis for at least 6 weeks despite treatment with H1 antihistamines prior to commencing non-PBS subsidised treatment with this drug for this condition, AND
- Patient must have documented history of failure to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
Must be treated by a dermatologist; OR
Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).
A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:
1) a H2 receptor antagonist (150 mg twice per day); or
2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
3) doxepin (up to 25 mg three times a day)
If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.
A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial Grandfather PBS Authority Application - Supporting Information Form which must include:
(i) demonstration of failure to achieve an adequate response to standard therapy; and
(ii) drug names and doses of standard therapies that the patient has failed; and
(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

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- OMALIZUMAB

Note Special Pricing Arrangements apply.

Authority required
Uncontrolled severe allergic asthma
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, AND
- Patient must have a duration of asthma of at least 1 year, AND
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, AND
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, AND
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 6 to less than 12 years.

Treatment criteria:
- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:
- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:
(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, Cromolyn sodium or nedocromil may be used as an alternative; AND
(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.
If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used). AND
(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:
   (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
   (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
   (iii) acknowledgement signed by a parent or authorised guardian; and
   (c) a copy of the IgE pathology report; and
   (d) a completed Asthma Control Questionnaire (ACQ-5) or the Asthma Control Questionnaire interviewer administered version (ACQ-IA) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the prescriber's signature.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December...
2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline measurements are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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**Authority required**

Uncontrolled severe allergic asthma

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR
(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of maintenance oral corticosteroid dose; and
Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, as minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:

Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-1A, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-1A, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.
Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction or Grandfather treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing or Grandfather restrictions.

Note:
Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing or grandfather restrictions may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2016, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have had, prior to commencement of omalizumab, a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, AND
- Patient must have had a duration of asthma of at least 1 year prior to commencement of omalizumab, AND
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, AND
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to omalizumab therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- Patient must have demonstrated an adequate response to treatment.

Population criteria:
- Patient must be aged 6 to less than 12 years.

Treatment criteria:
- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:
- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:
(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND
(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient’s records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:
(i) a reduction in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire Interviewer Administered (ACQ-IA) score of at least 0.5;
(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or
(iii) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

Patients will be eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.
Patients may qualify for PBS-subsidised treatment under this restriction once only.
A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for an initial course of omalizumab of up to 24 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Paediatric Grandfather Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and
(iii) acknowledgement signed by a parent or authorised guardian.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.
Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com
Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA
Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment restriction and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy.
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Grandfather patients:
Paediatric patients who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 December 2016 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this restriction. Approval will be based on the criteria included in the grandfather restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic...
corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe
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omalizumab 150 mg/mL injection, 1 mL syringe
10973M

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### OMALIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe allergic asthma

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Population criteria:**
- Patient must be aged 12 years or older.

Optimised asthma therapy includes:
- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.
The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(iii) the signed patient or parent/guardian acknowledgement; and
(c) the IgE pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a ‘mepolizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new...
baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

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### Authority required

Uncontrolled severe allergic asthma

#### Treatment Phase: Initial treatment - balance of supply

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note:** Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

- Department of Human Services
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

#### Authority required

Uncontrolled severe allergic asthma

#### Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of severe allergic asthma, AND
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**
- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.
At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauono@novartis.com

Note It is recommended that any application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (during operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a ‘mepolizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:
Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements of the Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history. Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
**RESPIRATORY SYSTEM**

**Authority required**

Uncontrolled severe allergic asthma

**Treatment Phase:** Continuing treatment - balance of supply

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**COUGH AND COLD PREPARATIONS**

**EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS**

**Mucolytics**

**Dornase Alfa**

- **Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

- **Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

5740
Cystic fibrosis

**Population criteria:**
- Patient must be 5 years of age or older.
- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:
1. (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
2. (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)**

5634
Cystic fibrosis

**Clinical criteria:**
- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measured by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**
- Patient must be less than 5 years of age.
Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)**

5635
Cystic fibrosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**
- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

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**dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

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**MANNITOL**

**Note** This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

5799
Cystic fibrosis

**Clinical criteria:**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

**Population criteria:**
- Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:
1. the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**
2. the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**MANNITOL** Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers

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**OTHER RESPIRATORY SYSTEM PRODUCTS**

**IVACAFTOR**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
**Authority required**

Cystic fibrosis

**Treatment Phase: Initial treatment - New patients**

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

**Strong CYP3A4 inducers:** avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

**Moderate CYP3A4 inducers:** bosentan, efavirenz, etravirine, modafinil, nafcillin

**Weak CYP3A4 inducers:** armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
3. a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
5. the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older.

Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
6. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
7. a copy of a sweat chloride result; and
8. height and weight measurements at the time of application; and
9. a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

**Authority required**

Cystic fibrosis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month’s supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan,
indinavir, lriage, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenamivir, amsulpride, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form;
2. a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
3. the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
4. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
5. height and weight measurements at the time of application; and
6. a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

Ivacaftor 150 mg tablet, 56

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### IVACAFTOR

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

- **Authority required**
  - Cystic fibrosis
  - Treatment Phase: Initial treatment - New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, iraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenamivir, amsulpride, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
3. a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
Complex Drugs
Department of Human Services

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

(b) Clinical criteria:

1. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

(f) Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

(g) Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

(h) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(i) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir,itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(j) Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

(k) Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

(l) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(m) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(n) Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

(o) Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

(p) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(q) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(r) Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

(s) Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

(t) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(u) Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fosamprenavir, imatinib, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

(v) Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

(w) Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.
Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

• Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

• Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

• Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND

• Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, AND

• Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND

• Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, AND

• Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

• Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mifepradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, modafinil, nefazodone, nelfinavir, nafcillin, ondansetron, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
3. an acknowledgement signed by a parent, or authorised guardian if applicable; and
4. a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
5. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
6. a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
7. height and weight measurements at the time of application; and
8. height and weight measurements performed immediately prior to commencement of ivacaftor; and
9. a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
10. a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and
11. dates of prior ivacaftor therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
### Highly Specialised Drugs Program (Public Hospital)

#### ivacaftor 75 mg granules, 4 x 14 sachets

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#### ivacaftor 50 mg granules, 4 x 14 sachets

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### ALL OTHER THERAPEUTIC PRODUCTS

#### Iron chelating agents

### DEFERASIROX

**Note**: Special Pricing Arrangements apply. Authority required (STREAMLINED)

#### Chronic iron overload

**Clinical criteria**:
- Patient must have a disorder of erythropoiesis.

### deferasirox 125 mg dispersible tablet, 28

#### deferasirox 500 mg dispersible tablet, 28

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### deferasirox 250 mg dispersible tablet, 28

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### DEFERIPRONE

**Authority required (STREAMLINED)**

#### Iron overload

**Clinical criteria**:
- Patient must have thalassaemia major, AND
- Patient must be unable to take desferrioxamine therapy.

### deferiprone 500 mg tablet, 100

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### deferiprone 100 mg/mL oral liquid, 250 mL

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### DESFERRIOXAMINE

**Authority required (STREAMLINED)**

#### Disorders of erythropoiesis

**Clinical criteria**:
- The condition must be associated with treatment-related chronic iron overload.
desferrioxamine mesilate 2 g injection, 1 vial

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Desferrioxamine mesilate 500 mg injection, 10 vials

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Drugs for treatment of hyperkalemia and hyperphosphatemia

**LANTHANUM**

**Authority required (STREAMLINED)**
5530
Hyperphosphataemia
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

**LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90**

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**LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90**

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**LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90**

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**SEVELAMER**

**Authority required (STREAMLINED)**
5530
Hyperphosphataemia
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

**Sevelamer hydrochloride 800 mg tablet, 180**

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**SUCROFERREIC OXYHYDROXIDE**

**Authority required (STREAMLINED)**
5530
Hyperphosphataemia
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.
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<td>..</td>
<td>*753.46</td>
<td>Velphoro [FN]</td>
<td></td>
</tr>
</tbody>
</table>
## Highly Specialised Drugs Program (Community Access)

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiinfectives for Systemic Use</td>
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<td>Antivirals for Systemic Use</td>
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<td>1276</td>
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<td>Antipsychotics</td>
<td>1276</td>
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</tbody>
</table>
### ANTIINFECTIVES FOR SYSTEMIC USE

#### ANTIVIRALS FOR SYSTEMIC USE

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

- **GANCICLOVIR**
  - **Authority required (STREAMLINED)**
  - **5000**
  - **Cytomegalovirus retinitis**
  - **Clinical criteria:**
    - Patient must be severely immunocompromised, including due to HIV infection.
  - **ganciclovir 500 mg injection, 5 vials**
    - **10328N**
      - Max Qty Packs: 2
      - No. of Rpts: 1
      - Premium $: 560.43
      - DPMQ $: 38.80
      - MRVSN $: 38.80
      - Brand Name and Manufacturer: Cymevene [RO]

- **VALGANCICLOVIR**
  - **Authority required (STREAMLINED)**
  - **4980**
  - **Cytomegalovirus retinitis**
  - **Clinical criteria:**
    - Patient must have HIV infection.
  - **valganciclovir 450 mg tablet, 60**
    - **10306K**
      - Max Qty Packs: 2
      - No. of Rpts: 5
      - Premium $: 3631.45
      - DPMQ $: 38.80
      - MRVSN $: 38.80
      - Brand Name and Manufacturer: Valcyte [RO], Valganciclovir Juno [JU], Valganciclovir Sandoz [SZ], Valganciclovir Mylan [AF]
  - **valganciclovir 50 mg/mL powder for oral liquid, 100 mL**
    - **10277X**
      - Max Qty Packs: 11
      - No. of Rpts: 5
      - Premium $: #4396.02
      - DPMQ $: 38.80
      - MRVSN $: 38.80
      - Brand Name and Manufacturer: Valcyte [RO]

#### Phosphonic acid derivatives

- **FOSCARNET**
  - **Authority required (STREAMLINED)**
  - **4980**
  - **Cytomegalovirus retinitis**
  - **Clinical criteria:**
    - Patient must have HIV infection.
    - **Authority required (STREAMLINED)**
  - **4973**
  - **Herpes simplex virus infection**
  - **Clinical criteria:**
    - The condition must be aciclovir resistant, AND
    - Patient must have HIV infection.
  - **Foscarnet Sodium I.V. infusion 24 mg per mL, 250 mL bottle, 6**
    - **10352W**
      - Max Qty Packs: 1
      - No. of Rpts: 1
      - Premium $: 1165.78
      - DPMQ $: 38.80
      - MRVSN $: 38.80
      - Brand Name and Manufacturer: Foscavir [LM]

#### Protease inhibitors

- **ATAZANAVIR**
  - **Authority required (STREAMLINED)**
  - **4512**
  - **HIV infection**
  - **Treatment Phase: Initial**
  - **Clinical criteria:**
    - Patient must be antiretroviral treatment naive, AND
    - The treatment must be in combination with other antiretroviral agents.
  - **Authority required (STREAMLINED)**
  - **4454**
  - **HIV infection**
  - **Treatment Phase: Continuing**
  - **Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### atazanavir 150 mg capsule, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>..</td>
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<td>38.80</td>
<td>Reyataz [BQ]</td>
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### atazanavir 200 mg capsule, 60

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<tbody>
<tr>
<td>10349Q</td>
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### atazanavir 300 mg capsule, 30

<table>
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<tbody>
<tr>
<td>10321F</td>
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<td>..</td>
<td>*1038.43</td>
<td>38.80</td>
<td>Reyataz [BQ]</td>
</tr>
</tbody>
</table>

#### ATAZANAVIR + COBICISTAT

**Authority required (STREAMLINED)**

4512

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### atazanavir 300 mg + cobicistat 150 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>10692R</td>
<td>5</td>
<td>..</td>
<td>*1116.57</td>
<td>38.80</td>
<td>Evotaz [BQ]</td>
</tr>
</tbody>
</table>

#### DARUNAVIR

**Authority required (STREAMLINED)**

5094

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.
- Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

### darunavir 600 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>10329P</td>
<td>5</td>
<td>..</td>
<td>*2039.69</td>
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<td>Prezista [JC]</td>
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### darunavir 150 mg tablet, 240

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<tr>
<td>10287K</td>
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<td>1043.27</td>
<td>38.80</td>
<td>Prezista [JC]</td>
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</table>

#### DARUNAVIR

**Authority required (STREAMLINED)**

4313

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**darunavir 800 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td>10367P</td>
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<td>..</td>
<td>1375.51</td>
<td>Prezista [JC]</td>
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- **FOSAMPRENAVIR**  
  **Authority required (STREAMLINED)**  
  **4512**  
  HIV infection  
  **Clinical criteria:**  
  - Patient must be antiretroviral treatment naive, **AND**  
  - The treatment must be in combination with other antiretroviral agents.  
  **Authority required (STREAMLINED)**  
  **4454**  
  HIV infection  
  **Clinical criteria:**  
  - Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**  
  - The treatment must be in combination with other antiretroviral agents.

- **fosamprenavir 700 mg tablet, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>10337C</td>
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<td>5</td>
<td>..</td>
<td>756.37</td>
<td>Telzir [VI]</td>
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</tbody>
</table>

- **INDINAVIR**  
  **Authority required (STREAMLINED)**  
  **4512**  
  HIV infection  
  **Clinical criteria:**  
  - Patient must be antiretroviral treatment naive, **AND**  
  - The treatment must be in combination with other antiretroviral agents.  
  **Authority required (STREAMLINED)**  
  **4454**  
  HIV infection  
  **Clinical criteria:**  
  - Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**  
  - The treatment must be in combination with other antiretroviral agents.

- **indinavir 400 mg capsule, 180**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tr>
<td>10363K</td>
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<td>5</td>
<td>..</td>
<td>906.23</td>
<td>Crixivan 400 mg [MK]</td>
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</table>

- **RITONAVIR**  
  **Authority required (STREAMLINED)**  
  **4512**  
  HIV infection  
  **Clinical criteria:**  
  - Patient must be antiretroviral treatment naive, **AND**  
  - The treatment must be in combination with other antiretroviral agents.  
  **Authority required (STREAMLINED)**  
  **4454**  
  HIV infection  
  **Clinical criteria:**  
  - Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**  
  - The treatment must be in combination with other antiretroviral agents.
ANTIINFECTIVES FOR SYSTEMIC USE

<table>
<thead>
<tr>
<th>Name</th>
<th>Formulation</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td><strong>ritonavir</strong></td>
<td>600 mg/7.5 mL oral liquid, 90 mL</td>
<td>10300D</td>
<td>10</td>
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<td>*906.25</td>
<td>38.80</td>
<td>Norvir [VE]</td>
</tr>
<tr>
<td></td>
<td>100 mg tablet, 30</td>
<td>10273Q</td>
<td>24</td>
<td>..</td>
<td>*978.19</td>
<td>38.80</td>
<td>Norvir [VE]</td>
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</tbody>
</table>

**SAQUINAVIR**

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**saquinavir 500 mg tablet, 120**

10335Y

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $  | MRVSN $ | Brand Name and Manufacturer
--------------|-------------|-----------|---------|---------|-----------------------------|
2             | 5           | ..        | *1006.13| 38.80   | Invirase [RO]               |

**TIPRANAVIR**

Authority required (STREAMLINED)

5764

HIV infection

Clinical criteria:
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- The treatment must be co-administered with 200 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**tipranavir 250 mg capsule, 120**

10344K

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $  | MRVSN $ | Brand Name and Manufacturer
--------------|-------------|-----------|---------|---------|-----------------------------|
2             | 5           | ..        | *1675.07| 38.80   | Aptivus [BY]                |

Nucleoside and nucleotide reverse transcriptase inhibitors

**ABACAVIR**

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.
### ADEFOVIR DIPIVOXIL

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antiepadnaviral therapy.

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
<th>Chronic hepatitis B infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>4490</td>
<td>Patient must have cirrhosis, <strong>AND</strong> Patient must have failed antiepadnaviral therapy, <strong>AND</strong> Patient must have repeatedly elevated serum ALT levels while on concurrent antiepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; <strong>OR</strong> Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antiepadnaviral therapy, except in patients with evidence of poor compliance.</td>
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### DIDANOSINE

**Authority required (STREAMLINED)**

<table>
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<td>Treatment Phase: Initial</td>
<td>Patient must be antiretroviral treatment naive, <strong>AND</strong> The treatment must be in combination with other antiretroviral agents.</td>
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**Authority required (STREAMLINED)**

<table>
<thead>
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<th>4454</th>
<th>HIV infection</th>
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</thead>
<tbody>
<tr>
<td>Treatment Phase: Continuing</td>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection, <strong>AND</strong> The treatment must be in combination with other antiretroviral agents.</td>
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### EMTRICITABINE

**Authority required (STREAMLINED)**

<table>
<thead>
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<th>4512</th>
<th>HIV infection</th>
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</thead>
<tbody>
<tr>
<td>Treatment Phase: Initial</td>
<td>Clinical criteria:</td>
</tr>
</tbody>
</table>

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### Abacavir 300 mg tablet, 60

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>10294T</td>
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<td>5</td>
<td>*564.39</td>
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<td>Ziagen [VI]</td>
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### Abacavir 20 mg/mL oral liquid, 240 mL

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<tr>
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<td>*656.35</td>
<td>38.80</td>
<td>Ziagen [VI]</td>
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### Adefovir dipivoxil 10 mg tablet, 30

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<tr>
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<td>*1097.15</td>
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<td>APO-Adefovir [TX] A Hepsera [GI]</td>
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### Didanosine 250 mg enteric capsule, 30

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<tr>
<td>10364L</td>
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<td>5</td>
<td>*410.73</td>
<td>38.80</td>
<td>Videx EC [BQ]</td>
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### Didanosine 400 mg enteric capsule, 30

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10313T</td>
<td>2</td>
<td>5</td>
<td>*652.89</td>
<td>38.80</td>
<td>Videx EC [BQ]</td>
</tr>
</tbody>
</table>
• Patient must be antiretroviral treatment naive, AND
• The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**
HIV infection
Treatment Phase: Continuing

**Clinical criteria:**
• Patient must have previously received PBS-subsidised therapy for HIV infection, AND
• The treatment must be in combination with other antiretroviral agents.

**emtricitabine 200 mg capsule, 30**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emtriva [GI]</td>
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<td>38.80</td>
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</tr>
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</table>

**ENTECAVIR**

**Authority required (STREAMLINED)**

**4993**
Chronic hepatitis B infection

**Clinical criteria:**
• Patient must not have cirrhosis, AND
• Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
• Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND
• Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

** Authority required (STREAMLINED)**

**5036**
Chronic hepatitis B infection

**Clinical criteria:**
• Patient must have cirrhosis, AND
• Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note:** PBS-subsidised entecavir monohydrate must be used as monotherapy.

**ENTECAVIR**

**Authority required (STREAMLINED)**

**5044**
Chronic hepatitis B infection

**Clinical criteria:**
• Patient must not have cirrhosis, AND
• Patient must have failed lamivudine, AND
• Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
• Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Authority required (STREAMLINED)**

**5037**
Chronic hepatitis B infection

**Clinical criteria:**
• Patient must have cirrhosis, AND
• Patient must have failed lamivudine, AND
• Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.
### LAMIVUDINE

**Authority required (STREAMLINED)**

#### 4512

**HIV infection**

**Treatment Phase: Initial**

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### 4454

**HIV infection**

**Treatment Phase: Continuing**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### LAMIVUDINE

**Authority required (STREAMLINED)**

#### 4993

**Chronic hepatitis B infection**

**Clinical criteria:**
- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; **OR**
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

#### 5036

**Chronic hepatitis B infection**

**Clinical criteria:**
- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

---

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zetlam [AF]</td>
<td>*80.55</td>
<td>38.80</td>
<td></td>
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<tr>
<td>Zeffix [RW]</td>
<td>*81.75</td>
<td>38.80</td>
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</table>
STAVUDINE

**Authority required (STREAMLINED)**

- **4512**
  - HIV infection
  - Treatment Phase: Initial
  - **Clinical criteria:**
    - Patient must be antiretroviral treatment naive, **AND**
    - The treatment must be in combination with other antiretroviral agents.

- **4454**
  - HIV infection
  - Treatment Phase: Continuing
  - **Clinical criteria:**
    - Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
    - The treatment must be in combination with other antiretroviral agents.

**stavudine 40 mg capsule, 60**

<table>
<thead>
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<th>Premium $</th>
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**stavudine 30 mg capsule, 60**

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</table>

TENOFOVIR

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

- **6998**
  - HIV infection
  - Treatment Phase: Initial
  - **Clinical criteria:**
    - Patient must be antiretroviral treatment naive, **AND**
    - The treatment must be in combination with other antiretroviral agents.

- **6982**
  - HIV infection
  - Treatment Phase: Continuing
  - **Clinical criteria:**
    - Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
    - The treatment must be in combination with other antiretroviral agents.

- **6980**
  - Chronic hepatitis B infection
  - **Clinical criteria:**
    - Patient must have cirrhosis, **AND**
    - Patient must be nucleoside analogue naive, **AND**
    - Patient must have detectable HBV DNA, **AND**
    - The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)**

- **6992**
  - Chronic hepatitis B infection
  - **Clinical criteria:**
    - Patient must not have cirrhosis, **AND**
    - Patient must be nucleoside analogue naive, **AND**
    - Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
    - Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
    - Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised anthepadnaviral therapy.

**Authority required (STREAMLINED)**

**6983**

Chronic hepatitis B infection

**Clinical criteria:**
- Patient must have cirrhosis, **AND**
- Patient must have failed anthepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised anthepadnaviral therapy.

---

**ZIDOVUDINE**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

---

**Zidovudine 100 mg capsule, 100**

<table>
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**Zidovudine 50 mg/5 mL oral liquid, 200 mL**

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</table>
### Efavirenz

**Authority required (STREAMLINED)**

**4512**

HIV infection

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Etravirine

**Authority required (STREAMLINED)**

**5014**

HIV infection

**Clinical criteria:**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

### Nevirapine

**Authority required (STREAMLINED)**

**4526**

HIV infection

**Clinical criteria:**
- Patient must have been stabilised on nevirapine immediate release, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.
### NEVIRAPINE

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### nevirapine 400 mg modified release tablet, 30

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<tbody>
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<td>*334.01</td>
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<td>* Nevirapine XR APOTEX [TX]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Viramune XR [BY]</td>
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</table>

#### nevirapine 10 mg/mL oral liquid, 240 mL

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<td>Viramune [BY]</td>
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#### nevirapine 10 mg/mL oral liquid, 240 mL

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<td>* Viramune [BY]</td>
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### RILPIVIRINE

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### rilpivirine 25 mg tablet, 30

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<tr>
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### ABACAVIR + LAMIVUDINE

**Authority required (STREAMLINED)**

**4527**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Population criteria:**
- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

**4528**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**
Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

**Population criteria:**
- Patient must be aged 12 years or older, AND
- Patient must weigh 40 kg or more.

**abacavir 600 mg + lamivudine 300 mg tablet, 30**

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**ABACAVIR + LAMIVUDINE + ZIDOVUDINE**

**Authority required (STREAMLINED)**

**4495**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive.

**Population criteria:**
- Patient must be aged 12 years or older, AND
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

**4480**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**
- Patient must be aged 12 years or older, AND
- Patient must weigh 40 kg or more.

**abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60**

<table>
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**DARUNAVIR + COBICISTAT**

**Authority required (STREAMLINED)**

**6413**

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, AND
- The treatment must be in combination with other antiretroviral agents, AND
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**6428**

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, AND
- The treatment must be in combination with other antiretroviral agents, AND
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**6377**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**
- The treatment must be in addition to optimised background therapy, AND
- The treatment must be in combination with other antiretroviral agents, AND
- The treatment must not be in combination with ritonavir, AND
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.
Note: The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

darunavir 800 mg + cobicistat 150 mg tablet, 30 pack

HIV infection

Clinical criteria:
- Patient must be antiretroviral treatment naive.

Population criteria:
- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

<table>
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**DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE**

**Authority required (STREAMLINED)**

HIV infection

Clinical criteria:
- Patient must be antiretroviral treatment naive.

Population criteria:
- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

**Authority required (STREAMLINED)**

<table>
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**EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE**

**Authority required (STREAMLINED)**

HIV infection

Clinical criteria:
- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**EMTRICITABINE + TENOFOVIR ALAFENAMIDE**

**Authority required (STREAMLINED)**

HIV infection

Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

<table>
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# Antiinfectives for Systemic Use

## Emtricitabine 200 mg + Tenofovir Alafenamide 10 mg Tablet, 30

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<td>2</td>
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<td>$1500.85</td>
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## Emtricitabine 200 mg + Tenofovir Alafenamide 25 mg Tablet, 30

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<td>..</td>
<td>$1500.85</td>
<td>38.80</td>
<td>Descovy [GI]</td>
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</table>

### Lamivudine + Zidovudine

**Authority required (STREAMLINED)**

#### 4512

**HIV infection**  
**Treatment Phase:** Initial  
**Clinical criteria:**  
- Patient must be antiretroviral treatment naive, **AND**  
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

#### 4454

**HIV infection**  
**Treatment Phase:** Continuing  
**Clinical criteria:**  
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**  
- The treatment must be in combination with other antiretroviral agents.

## Lamivudine 150 mg + Zidovudine 300 mg Tablet, 60

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### Lopinavir + Ritonavir

**Authority required (STREAMLINED)**

#### 4512

**HIV infection**  
**Treatment Phase:** Initial  
**Clinical criteria:**  
- Patient must be antiretroviral treatment naive, **AND**  
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

#### 4454

**HIV infection**  
**Treatment Phase:** Continuing  
**Clinical criteria:**  
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**  
- The treatment must be in combination with other antiretroviral agents.

## Lopinavir 100 mg + Ritonavir 25 mg Tablet, 60

<table>
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<tr>
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<td>$361.21</td>
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<td>Kaletra [VE]</td>
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## Lopinavir 200 mg + Ritonavir 50 mg Tablet, 120

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<td>$1408.93</td>
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<td>Kaletra [VE]</td>
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</table>

## Lopinavir 400 mg/5 mL + Ritonavir 100 mg/5 mL Oral Liquid, 60 mL

<table>
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<tbody>
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<td>$1329.55</td>
<td>38.80</td>
<td>Kaletra [VE]</td>
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</table>

### Tenofovir + Emtricitabine

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

#### 6985

**HIV infection**  
**Treatment Phase:** Initial
Clinical criteria:
• Patient must be antiretroviral treatment naive, AND
• The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**6986**
HIV infection
Treatment Phase: Continuing
Clinical criteria:
• Patient must have previously received PBS-subsidised therapy for HIV infection, AND
• The treatment must be in combination with other antiretroviral agents.

**tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30**

<table>
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**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

<table>
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**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

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<tr>
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<td>1268.25</td>
<td>38.80</td>
<td>* Truvada [Gl]</td>
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**TENOFOVIR + EMTRICITABINE + EFAVIRENZ**

**Authority required (STREAMLINED)**

**4522**
HIV infection
Treatment Phase: Initial
Clinical criteria:
• Patient must be antiretroviral treatment naive.

**4470**
HIV infection
Treatment Phase: Continuing
Clinical criteria:
• Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30**

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**TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**

**Authority required (STREAMLINED)**

**4522**
HIV infection
Treatment Phase: Initial
Clinical criteria:
• Patient must be antiretroviral treatment naive.

**4470**
HIV infection
Treatment Phase: Continuing
Clinical criteria:
• Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

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**TENOFOVIR + EMTRICITABINE + RILPIVIRINE**

**Authority required (STREAMLINED)**

**4522**
HIV infection
Treatment Phase: Initial
Clinical criteria:
• Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

4470
HIV infection
Treatment Phase: Continuing

**Clinical criteria:**
• Patient must have previously received PBS-subsidised therapy for HIV infection.

**Tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg tablet, 30**

10314W

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**TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**

**Authority required (STREAMLINED)**

4522
HIV infection
Treatment Phase: Initial

**Clinical criteria:**
• Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

4470
HIV infection
Treatment Phase: Continuing

**Clinical criteria:**
• Patient must have previously received PBS-subsidised therapy for HIV infection.

**Tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

11114Y

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**Other antivirals**

**Dolutegravir**

**Authority required (STREAMLINED)**

4512
HIV infection
Treatment Phase: Initial

**Clinical criteria:**
• Patient must be antiretroviral treatment naive, **AND**
• The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454
HIV infection
Treatment Phase: Continuing

**Clinical criteria:**
• Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
• The treatment must be in combination with other antiretroviral agents.

**Dolutegravir 50 mg tablet, 30**

10283F

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**Enfuvirtide**

**Authority required (STREAMLINED)**

5014
HIV infection

**Clinical criteria:**
• The treatment must be in addition to optimised background therapy, **AND**
• The treatment must be in combination with other antiretroviral agents, **AND**
• Patient must be antiretroviral experienced, **AND**
• Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.
### MARAVIROC

**Authority required (STREAMLINED)**

**5008**

**HIV infection**

**Clinical criteria:**
- Patient must be infected with CCR5-tropic HIV-1, **AND**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

#### maraviroc 300 mg tablet, 60

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### Raltegravir

**Authority required (STREAMLINED)**

**4512**

**HIV infection**

**Treatment Phase: Initial**

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

**HIV infection**

**Treatment Phase: Continuing**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### raltegravir 400 mg tablet, 60

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### Raltegravir

**Authority required (STREAMLINED)**

**4275**

**HIV infection**

**Treatment Phase: Initial**

**Clinical criteria:**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have a CD4 count of less than 500 per cubic millimetre; OR
- Patient must have symptomatic HIV disease.

**Population criteria:**
- Patient must be aged 2 years or older.

**Authority required (STREAMLINED)**

**4274**

**HIV infection**

**Treatment Phase: Continuing**

**Clinical criteria:**
- The treatment must be in combination with other antiretroviral agents, **AND**
• Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, AND
• Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**
• Patient must be aged 2 years or older.

**raltegravir 100 mg chewable tablet, 60**

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**raltegravir 25 mg chewable tablet, 60**

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**IMMUNOSTIMULANTS**

**Interferons**

### INTERFERON ALFA-2A

**Authority required (STREAMLINED)**

#### 4993

Chronic hepatitis B infection

**Clinical criteria:**
• Patient must not have cirrhosis, AND
• Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
• Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND
• Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

#### 5036

Chronic hepatitis B infection

**Clinical criteria:**
• Patient must have cirrhosis, AND
• Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe**

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**interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe**

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### INTERFERON ALFA-2B

**Authority required (STREAMLINED)**

#### 4993

Chronic hepatitis B infection

**Clinical criteria:**
• Patient must not have cirrhosis, AND
• Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
• Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND
• Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

**Authority required (STREAMLINED)**

#### 5036

Chronic hepatitis B infection

**Clinical criteria:**
• Patient must have cirrhosis, AND
• Patient must have detectable HBV DNA.
Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL**

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**interferon alfa-2b 18 million units/3 mL injection, 3 mL vial**

<table>
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**interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL**

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**interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL**

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**interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials**

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**interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial**

<table>
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**PEGINTERFERON ALFA-2A**

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Authority required (STREAMLINED)**

**5010** Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must not have previously received peginterferon alfa therapy for the treatment of hepatitis B, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; **OR**
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

**5067** Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be limited to 1 course of treatment for a maximum duration of 48 weeks.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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NERVOUS SYSTEM

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

Authority required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:
- Patient must have previously received PBS-subsidised therapy with this drug for this condition, AND
- Patient must have completed at least 18 weeks therapy, AND
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, AND
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

### clozapine 200 mg tablet, 100

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### clozapine 25 mg tablet, 100

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### clozapine 100 mg tablet, 100

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### clozapine 50 mg tablet, 100

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### clozapine 50 mg/mL oral liquid, 100 mL

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Botulinum Toxin Program

MUSCULO-SKELETAL SYSTEM ................................................................. 1278

MUSCLE RELAXANTS .............................................................................. 1278
MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS ..................... 1278
MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

Other muscle relaxants, peripherally acting agents

**BOTULINUM TOXIN TYPE A**

*Caution* Contraindications to treatment include known sensitivity to botulinum toxin.

*Note* The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5221

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**Population criteria:**

- Patient must be aged 12 years or older.

**Botulinum toxin type A 100 units injection, 1 vial**

<table>
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<th>No. of Rpts</th>
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**BOTULINUM TOXIN TYPE A**

*Caution* Contraindications to treatment include known sensitivity to botulinum toxin.

*Note* The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5406

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a plastic surgeon; **OR**
- Must be treated by a rehabilitation specialist.

**Botulinum toxin type A 100 units injection, 1 vial**

<table>
<thead>
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**BOTULINUM TOXIN TYPE A**

*Caution* Contraindications to treatment include known sensitivity to botulinum toxin.

*Note* The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

*Note* Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

5409

Urinary incontinence

**Clinical criteria:**

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**
- The condition must be inadequately controlled by anti-cholinergic therapy, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
- Patient must have multiple sclerosis; **OR**
- Patient must have a spinal cord injury; **OR**
- Patient must be aged 18 years or older and have spina bifida.

**Treatment criteria:**

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<thead>
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<td>Botox [AG]</td>
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</table>
- Must be treated by a urologist; OR
- Must be treated by a urologist.

**botulinum toxin type A 100 units injection, 1 vial**

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</table>

### BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5359**

Dynamic equinus foot deformity

**Clinical criteria:**
- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**
- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

**5407**

Dynamic equinus foot deformity

**Clinical criteria:**
- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

### botulinum toxin type A 100 units injection, 1 vial

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### BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**5262**

Chronic migraine

**Treatment criteria:**
- Must be treated by a neurologist.

**Clinical criteria:**
- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

**Population criteria:**
- Patient must be aged 18 years or older.

Prophylactic migraine medications are propanolol, amitriptylin, methsergide, pizotifen, cyproheptadine or topiramate.
**Botulinum Toxin Type A**

**Caution**
Contraindications to treatment include known sensitivity to botulinum toxin.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**Urinary Incontinence**

**Treatment criteria:**
- Must be treated by a urologist; OR
- Must be treated by a gynaecologist.

**Clinical criteria:**
- The condition must be due to idiopathic overactive bladder, **AND**
- The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

**Population criteria:**
- Patient must be aged 18 years or older.

**Severe Primary Axillary Hyperhidrosis**

**Clinical criteria:**
- Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
- Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

**Population criteria:**
- Patient must be aged 12 years or older.

**Moderate to Severe Spasticity of the Upper Limb**

**Clinical criteria:**
- Patient must have cerebral palsy.

**Population criteria:**
- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
**MUSCULO-SKELETAL SYSTEM**

- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Authority required (STREAMLINED)**

**5261**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**
- Patient must have cerebral palsy, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Type A Neurotoxin Complex as a paediatric patient.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Note** Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

**Authority required (STREAMLINED)**

**5220**

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; **OR**
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; **OR**
- Must be treated by an orthopaedic surgeon; **OR**
- Must be treated by a rehabilitation specialist; **OR**
- Must be treated by a plastic surgeon; **OR**
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient’s medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

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**Botulinum toxin type A 100 units injection, 1 vial**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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**CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5220**

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; **OR**
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**
- Must be treated by a neurologist; **OR**
- Must be treated by an orthopaedic surgeon; **OR**
- Must be treated by a rehabilitation specialist; **OR**
- Must be treated by a plastic surgeon; **OR**
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient’s medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient’s medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

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clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

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**CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

*Caution* Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5405

Blepharospasm or hemifacial spasm

**Clinical criteria:**
- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

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clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

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**CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

*Caution* Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5406

Spasmodic torticollis

**Clinical criteria:**
- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

<table>
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clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

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</table>
### CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5359  
Dynamic equinus foot deformity

**Clinical criteria:**
- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**
- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

5332  
Dynamic equinus foot deformity

**Clinical criteria:**
- The condition must be due to spasticity, **AND**
- Patient must be an ambulant cerebral palsy patient, **AND**
- Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10981Y

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**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11006G

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### INCOCOBOTULINUMTOXINA

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5220  
Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.
The date of the stroke must be documented in the patient's medical records when treatment is initiated.
Standard management includes physiotherapy and/or oral spasticity agents.

**incobotulinumtoxina** 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

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**INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5360  
Blepharospasm

**Clinical criteria:**
- Patient must have blepharospasm.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**incobotulinumtoxina** 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

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**INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

5222  
Spasmodic torticollis

**Clinical criteria:**
- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**
- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**Population criteria:**
- Patient must be aged 18 years or older.

**incobotulinumtoxina** 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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Growth Hormone Program

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS........1286

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES............................ 1286
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES............................... 1286
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES**

**Somatropin and somatropin agonists**

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Short stature and slow growth

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; **OR**
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Population criteria:**
- Patient must be aged 3 years or older.

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation of the patient’s maturational or constitutional delay status; **AND**
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more. 

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin and sleep) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pelliculium), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

**Population criteria:**

- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Biochemical growth hormone deficiency and precocious puberty
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
- Patient must be aged 3 years or older.

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must not have a bone age of 2.5 years or less, AND
• Patient must not have a height greater than or equal to 155.0 cm, AND
• Patient must not have a bone age of 13.5 years or greater.

Population criteria:
• Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature due to short stature homeobox (SHOX) gene disorders**

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; **OR**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; **OR**
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be male and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
**Authority required**
Short stature associated with chronic renal insufficiency

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
- Patient must have a current height at or below the 25th percentile for age and sex, AND
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**
- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
- 1. A completed authority prescription form; AND
- 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
- 3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
  (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; OR
- 4. A bone age result performed within the last 12 months; AND
- 5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
- 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
- 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

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<th>No. of Rpts</th>
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<th>MRVSN $</th>
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**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

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Somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

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Somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

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**SOMATROPIN**

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
- Patient must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
Clinical criteria:
- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Initial treatment**

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR

- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven...
biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
• Patient must have hypothalamic obesity, AND
• Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
• Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomes abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficiencies were being adequately replaced.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Initial treatment
Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; AND
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must not have a bone age of 2.5 years or less, AND
• Patient must not have a height greater than or equal to 155.0cm, AND
• Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be a female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

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**Somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack**

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**SOMATROPIN**

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; **OR**
• Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over; females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have a current height below the 1st percentile for age and sex, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
• Patient must have a bone age of 2.5 years or less and an annual growth velocity of 6 cm per year or less, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
**Clinical criteria:**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.**

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels;
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Confirmation that the patient has precocious puberty; **AND**
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth
Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have other hypothalamic/pituitary hormone deficiencies (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

- Short stature associated with Turner syndrome

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
- Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0cm, AND
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

- Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more; OR

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Initial treatment**

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a current height at or below the 25th percentile for age and sex, AND

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
• Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
• Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
• Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be male and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must have a current height below the 1st percentile for age and sex, **AND**
• Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
• Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
• Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
• Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must not have a bone age of 2.5 years or less, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
• Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have a current height below the 1st percentile for age and sex, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have a current height below the 1st percentile for age and sex, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic posterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Clinical criteria:
• Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Clinical criteria:
• Patient must be female and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic posterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
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- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program. The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Initial treatment**

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must not have a bone age of 2.5 years or less, AND
• Patient must not have a height greater than or equal to 155.0cm, AND
• Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
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5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature due to short stature homeobox (SHOX) gene disorders
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with chronic renal insufficiency
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have a current height at or below the 25th percentile for age and sex, AND
**Treatment criteria:**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over 6 months; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over 6 months; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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c**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

<table>
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<tr>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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c**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

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c**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

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c**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

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somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge
9604L

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somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge
5820H

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somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge
6297K

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**SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; **OR**
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient’s maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed); Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central ectopia, ectopic or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; **OR**
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

**Treatment criteria:**
- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have documented clinical risk of hypoglycaemia, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program. The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,
clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,
clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypothalamic in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

- Patient must have hypothalamic obesity, AND

- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be female, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

**Authority required**

- Short stature associated with Turner syndrome
- Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
- Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
- Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
- Patient must have diagnosis consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnosis consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0cm, AND
- Patient must not have a bone age of 13.5 years or greater.
The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 26 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:
- 1. A completed authority prescription form; AND
- 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
- 3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
- 4. A bone age result performed within the last 12 months; AND
- 5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
- 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature due to short stature homebox (SHOX) gene disorders
Treatment Phase: Initial treatment
Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 6 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must be male and not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient’s condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient’s increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with chronic renal insufficiency
Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must have a current height at or below the 25th percentile for age and sex, AND
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
• Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
• Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be prepubertal.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

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**SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height below the 1st percentile for age and sex, **AND**
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; **OR**
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; **OR**
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**
Growth Hormone Program

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient’s maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have a current height below the 1st percentile for age and sex, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. The records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
• Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
• Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

**Treatment Phase:** Initial treatment

**Treatment criteria:**
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**
• Patient must have a chronological age of less than 2 years, AND
• Patient must have a documented clinical risk of hypoglycaemia, AND
• Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Biochemical growth hormone deficiency and precocious puberty
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, AND
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must have diabetes mellitus, AND
- Patient must not have a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.
**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have other hypothalamic/pituitary hormone deficiencies (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more. The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required
Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must not have a bone age of 2.5 years or less, AND
• Patient must not have a height greater than or equal to 155.0cm, AND
• Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:
• Patient must have a current height below the 1st percentile for age and sex, AND
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
• Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
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Clinical criteria:

- Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient’s condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a current height at or below the 25th percentile for age and sex, AND
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
- Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must be female, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR
- Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR
- Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
   (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
• Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, AND
• Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
• Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
• Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, AND
• Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient’s current height, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
• Patient must not have a chronological age of 18 years or greater.

Treatment criteria:
• Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND
4. The date that skeletal maturity was achieved (if applicable); AND
5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR
   (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist
6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with 1 repeat allowed) Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**Authority required**

Short stature and slow growth  
Treatment Phase: Continuing treatment  
Clinical criteria:  
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**  
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**  
- Patient must not have diabetes mellitus, **AND**  
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**  
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**  
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**  
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**  
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**  
- Patient must be female and must not have a height greater than or equal to 155.0cm.  

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).  
The authority application must be in writing and must include:  
1. A completed authority prescription form; **AND**  
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**  
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**  
4. A bone age result performed within the last 12 months; **AND**  
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).  
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency  
Treatment Phase: Continuing treatment  
Clinical criteria:  
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**  
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**  
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**  
- Patient must not have diabetes mellitus, **AND**  
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**  
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication ‘short stature due to biochemical growth hormone deficiency’.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must not have diabetes mellitus, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 13.5 years or greater, AND
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Growth Hormone Program

Authority required
Short stature and slow growth
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosage arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;
The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); **OR**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine,
Treatment Phase: Continuing treatment as a reclassified patient

- Growth retardation secondary to an intracranial lesion, or cranial irradiation

Clinical criteria:

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more. AND

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a...
continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must have been male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have been male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period, unless response was affected by a significant medical illness); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period, whichever applies), unless response was affected by a major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the [National Health (Growth Hormone Program) Special Arrangement 2015](https://www.gov.au) and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5μg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5μg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5μg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5μg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
• Patient must be female and menarche occurred before the chronological age of 10 years, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, OR
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special
Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; **OR**
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypothalamic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biological growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age above the 25th percentile for bone age and sex measured over both the 12 months and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Short stature associated with Turner syndrome

**Treatment Phase:** Continuing treatment as a reclassified patient

**Clinical criteria:**
Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**

3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

6. A bone age result performed within the last 12 months; **AND**

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **AND**

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **AND**

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**

Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; **OR**

Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **OR**
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

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**Somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack**

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**SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Short stature and slow growth

**Treatment Phase: Recomencement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed Growth Hormone Authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

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**Authority required**

**Short stature associated with biochemical growth hormone deficiency**

**Treatment Phase: Recommenecement of treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.
Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a reclassified patient (patient with a reclassification diagnosis or under review for reclassification); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note
If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note
If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommmencement of treatment as a reclassified patient should be submitted.
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a chronological age of 5 years or greater.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Biochemical growth hormone deficiency and precocious puberty
Treatment Phase: Recommencement of treatment
Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note
If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Recommencement of treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Short stature due to short stature homeobox (SHOX) gene disorders
Treatment Phase: Recommencement of treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis, OR
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Short stature and slow growth
Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a...
continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, or excretion of radiolabels such as DTPA, or by the height/creatinine formula; OR
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5 mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5 mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5 mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5 mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 physiological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and low plasma IGFBP-3 levels, OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk hypoplasia, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
4. Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category. Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 10 years; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more. The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth
Treatment Phase: Recommencement of treatment as a reclassified patient
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothyroidism obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
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- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; **OR**
   (b) Confirmation that the patient has a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months; **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a
continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; **OR**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; **OR**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**

- Patient must not have diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must not have a bone age of 2.5 years or less, **AND**

- Patient must not have a height greater than or equal to 155.0 cm, **AND**

- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescibption, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homebox (SHOX) gene disorders

**Treatment Phase: recommencement of treatment as a reclassified patient**

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homebox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; **OR**
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient’s increased risk of gonadoblastoma, AND

• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a height greater than or equal to 167.7cm; OR

• Patient must be female and must not have a height greater than or equal to 155.0cm, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient’s condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient’s increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

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**somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack**

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**SOMATROPIN**

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Population criteria:**

- Patient must be aged 3 years or older.
- The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a chronological age of 5 years or greater.

Population criteria:
- Patient must be aged 3 years or older.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication ‘short stature due to biochemical growth hormone deficiency’.

Authority required
Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature associated with Turner syndrome**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in mean growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.
- The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature due to short stature homeobox (SHOX) gene disorders**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in mean growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have a bone age of 13.5 years or greater, **AND**
- Patient must not have any condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND
• Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
• Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**
• Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**
Short stature and slow growth

**Treatment Phase:** Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm.

**Population criteria:**
- Patient must be aged 3 years or older.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 6cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than 6 months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); **OR**
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; **OR**
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be male, have a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must be male, have a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must be female, have a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must be female, have a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**
- Patient must be aged 3 years or older.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mIU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

**Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth**

**Treatment Phase:** Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a...
continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have a structural lesion that is not neoplastic; OR

- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must have other hypotalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

- Patient must have hypotalamic obesity, AND

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month period immediately prior to commencement of growth hormone treatment, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
- Patient must be aged 3 years or older.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a bone age of 13.5 years or greater, AND
- Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:
- Patient must be aged 3 years or older.
Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature due to short stature homeobox (SHOX) gene disorders
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with chronic renal insufficiency
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
   The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

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### somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

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### somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

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### SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Authority required**

- Short stature and slow growth
- Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/ cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature associated with biochemical growth hormone deficiency**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Growth retardation secondary to an intracranial lesion, or cranial irradiation**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must not have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Clinical criteria:**

• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature associated with Turner syndrome**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome – Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature due to short stature homeobox (SHOX) gene disorders**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome – Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 155.0 cm, OR
• Patient must be female and must not have a height greater than or equal to 167.7 cm; OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
• Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, OR
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
• Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and slow growth

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; **OR**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
- The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
- The authority application must be in writing and must include:
  1. A completed authority prescription form; AND
  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
  3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
  (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
  4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
  5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
  6. A bone age result performed within the last 12 months; AND
  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have been male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have been male, had a chronological age at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
   1. A completed authority prescription form; AND
   2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
   3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
   4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
   5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
   6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; **OR**
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; **OR**
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

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SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
• Patient must have a structural lesion that is not neoplastic; **OR**
• Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**
• Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, insulin).
clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypothalamic/isolation in association with pituitary deficits (ACTH, TSH, GnRHa or vasopressin/ADH deficiencies); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, AND

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRHa and/or vasopressin/ADH deficiencies), AND

- Patient must have hypothalamic obesity, AND

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficiencies; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a bone age of 13.5 years or greater, AND
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
**Authority required**
Short stature due to short stature homeobox (SHOX) gene disorders
Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; **OR**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Short stature associated with chronic renal insufficiency**

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note
If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

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**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

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**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

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somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

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No. of Rpts: 1  
Premium $: 655.80  
DPMQ $: 38.80  
MRVSN $: 38.80  
Brand Name and Manufacturer: Norditropin FlexPro [NO]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10468Y  
Max Qty Packs: 1  
No. of Rpts: 1  
Premium $: 655.80  
DPMQ $: 38.80  
MRVSN $: 38.80  
Brand Name and Manufacturer: Norditropin SimpleXx [NO]

### SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must not have diabetes mellitus, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
- Patient must have not been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Authority required
Short stature associated with Turner syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 13.5 years or greater, AND
- Patient must not have a height greater than or equal to 155.0 cm.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Authority required
Short stature due to short stature homeobox (SHOX) gene disorders
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatrics; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

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• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.
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SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND

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- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosage arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase:** Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
• Patient must be female and menarche occurred before the chronological age of 10 years, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopresin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have a structural lesion that is not neoplastic; OR

- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

• Patient must have hypothalamic obesity, AND

• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Continuing treatment as a reclassified patient
Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a bone age of 13.5 years or greater, AND
- Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in accordance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase:** Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient’s condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient’s increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND

**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**
- Patient must be male and not have a height greater than or equal to 167.7cm; OR
- Patient must be female and not have a height greater than or equal to 155.0cm; AND
- Patient must be male and not have a bone age of 15.5 years or more; OR
- Patient must be female and not have a bone age of 13.5 years or more.

**Population criteria:**
- Patient must be aged 3 years or older.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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**SOMATROPIN**

- **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
- Applications for authority to prescribe should be forwarded to:
  - Department of Human Services
  - Prior Written Approval of Complex Drugs
  - Reply Paid 9826
  - HOBART TAS 7001

**Authority required**
- Short stature and slow growth
- Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.
Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication ‘short stature due to biochemical growth hormone deficiency’.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Clinical criteria:**
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication ‘short stature due to biochemical growth hormone deficiency’.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Clinical criteria:**
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be female and must not have a bone age of 13.5 years or more; OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must not have a bone age of 13.5 years or greater, **AND**
• Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Continuing treatment**
Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be prepubertal.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: A patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

Authority required

Short stature and slow growth
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radiouclides such as DTPA, or by the height/creatinine formula; OR
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have been a female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have been a male, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed);

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic...
dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must have a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have, a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biological growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

• Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

• Patient must be female and menarche occurred before the chronological age of 10 years, AND

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more. Treatment criteria:

  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. The bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase:** Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; **OR**
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficiencies (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; **OR**
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a
Growth Hormone Program

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must not have a bone age of 2.5 years or less, AND

- Patient must not have a bone age of 13.5 years or greater, AND

- Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be prepubertal.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the short stature and slow growth.

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

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**somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

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**somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

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### SOMATROPIN

**Note:** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a...
continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**
- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**
- Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
Population criteria:

- Patient must be aged 3 years or older.
- The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
- The authority application must be in writing and must include:
  1. A completed authority prescription form; AND
  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
  3. Recent growth data (height and weight); AND
  4. A bone age result performed within the last 12 months; AND
  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment, an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Patient must not have diabetes mellitus, AND
Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
Patient must not have an active tumour or evidence of tumour growth or activity, AND
Patient must be male and must not have a bone age of 15.5 years or more; OR
Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatrics or endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.
- The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
- The authority application must be in writing and must include:
  1. A completed authority prescription form; AND
  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
  3. Recent growth data (height and weight, not older than three months); AND
  4. A bone age result performed within the last 12 months; AND
  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

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**Authority required**

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase: Recommenement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.
  
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

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**Authority required**

**Biochemical growth hormone deficiency and precocious puberty**

**Treatment Phase: Recommenement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**
• Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase:** Recommenement of treatment

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a
Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Special Arrangement 2015**

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

**Short stature associated with chronic renal insufficiency**

**Treatment Phase: Recomencement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the [National Health (Growth Hormone Program) Special Arrangement 2015](#) and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m², prescribers should seek recategorisation to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature and slow growth

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; **OR**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 187.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**
Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Recommencement of treatment as a reclassified patient
Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent anterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF/B-3 levels, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 8 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required
Growth retardation secondary to an intracranial lesion, or cranial irradiation
Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
• Patient must be female and menarche occurred before the chronological age of 10 years, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth
Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth. AND
• Patient must have had a lapse in growth hormone treatment. AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have a structural lesion that is not neoplastic; OR
• Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
• Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, AND
• Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
• Patient must have hypothalamic obesity, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
   (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
   (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencement of growth hormone treatment, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.
Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:
- Patient must be aged 3 years or older.
- The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
- The authority application must be in writing and must include:
  1. A completed authority prescription form; AND
  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
  3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
  4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
  5. Recent growth data (height and weight, not older than three months); AND
  6. A bone age result performed within the last 12 months; AND
- The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature due to short stature homeobox (SHOX) gene disorders
Treatment Phase: Recomencement of treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

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• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:
• Patient must be aged 3 years or older.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with chronic renal insufficiency
Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, have a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

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### SOMATROPIN

*Note* Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Short stature and slow growth

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
Note

If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

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<td>Short stature associated with biochemical growth hormone deficiency</td>
</tr>
<tr>
<td>Treatment Phase: Recommencement of treatment</td>
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</tbody>
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**Clinical criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### Authority required

**Growth retardation secondary to an intracranial lesion, or cranial irradiation**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### Authority required

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have sexual development on active hormone replacement therapy, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have a chronological age of 5 years or greater.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment, an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

**Short stature associated with Turner syndrome**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

**Short stature due to short stature homeobox (SHOX) gene disorders**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (46X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND

Patient must be male and must not have a bone age of 13.5 years or more, OR

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

Patient must be prepubertal.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication ‘short stature associated with chronic renal insufficiency’ undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**

- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

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**GH**

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• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m\(^2\)/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m\(^2\) measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the last 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

• Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must not have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

• Patient must not have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
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- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GhR/H or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have been, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have been, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have been, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 months and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be male and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Biochemical growth hormone deficiency and precocious puberty
Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

• Patient must be female and menarche occurred before the chronological age of 10 years, AND

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recomencement of treatment as a reclassified patient

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
• Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; **OR**
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; **OR**
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must not have a bone age of 2.5 years or less, **AND**
• Patient must not have a height greater than or equal to 155.0 cm, **AND**
• Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
• Patient must have had a lapse in growth hormone treatment, **AND**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness due to major surgery (e.g. renal transplant); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness due to major surgery (e.g. renal transplant); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness due to major surgery (e.g. renal transplant); **OR**

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• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
Growth Hormone Program

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more. Population criteria:

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND 6. Recent growth data (height and weight, not older than three months); AND 7. A bone age result performed within the last 12 months; AND 8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack**

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**SOMATROPIN**

*Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001*

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
Note

If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note:** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

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### Authority required

**Growth retardation secondary to an intracranial lesion, or cranial irradiation**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note:** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

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### Authority required

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
- Patient must have had a lapse in growth hormone treatment, AND

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• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Note

• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a chronological age of 5 years or greater.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note

If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

**Short stature associated with Turner syndrome**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness, OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.
• Patient must have had a lapse in growth hormone treatment, **AND**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; **OR**
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (46X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be female and must not have a bone age of 13.5 years or more, **AND**
• Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
• Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment, an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**
- Short stature associated with chronic renal insufficiency

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; **OR**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (46X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.
continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m²; AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more, AND

- Patient must be male and must not have a height greater than or equal to 167.7cm; OR

- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication ‘short stature associated with chronic renal insufficiency’ undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**Note:** recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature and slow growth

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

- Patient must have had a lapse in growth hormone treatment, AND

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

• Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be male, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midline hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, and low plasma IGF-1 levels; AND
• Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have evidence of biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, and low plasma IGF-1 levels; AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not be male and must not have a bone age of 15.5 years or more; OR
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not be male and must not have a bone age of 15.5 years or more; OR
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have evidence of biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
• Patient must have had a lapse in growth hormone treatment, **AND**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
• Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
• Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
• Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
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- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, \textbf{AND}
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; \textbf{OR}
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; \textbf{OR}
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; \textbf{OR}
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; \textbf{OR}
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; \textbf{OR}
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, \textbf{AND}
- Patient must not have diabetes mellitus, \textbf{AND}
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, \textbf{AND}
- Patient must not have an active tumour or evidence of tumour growth or activity, \textbf{AND}
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the \textbf{National Health (Growth Hormone Program) Special Arrangement 2015} and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; \textbf{AND}
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; \textbf{AND}
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; \textbf{OR}
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 8 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; \textbf{AND}
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; \textbf{AND}
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); \textbf{OR}
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; \textbf{OR}
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; \textbf{AND}
6. Recent growth data (height and weight, not older than three months); \textbf{AND}
7. A bone age result performed within the last 12 months; \textbf{AND}
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**Authority required**

Risks of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

**Treatment Phase:** Recomencement of treatment as a reclassified patient

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase:** Recomencement of treatment as a reclassified patient

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be male and must not have a bone age of 13.5 years or more. The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies, unless response was affected by a significant medical illness); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies, unless response was affected by major surgery (e.g. renal transplant)); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have other hypothalamic/pituitary hormone deficiencies (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Recommmencement of treatment as a reclassified patient

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have been an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months' worth of treatment (with up to 1 repeat allowed).

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months' worth of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a height greater than or equal to 167.7cm; OR

• Patient must be female and must not have a height greater than or equal to 155.0cm, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6
months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

### SOMATROPIN

**Note:** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Short stature and slow growth**

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**

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**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

<table>
<thead>
<tr>
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<th>Packs</th>
<th>No. of Rpts</th>
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**somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge**

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**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

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**somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge**

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**somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge**

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**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

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**somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge**

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<th>No. of Rpts</th>
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<td>655.80</td>
<td>38.80</td>
<td></td>
<td>Norditropin FlexPro [NO]</td>
</tr>
</tbody>
</table>
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**
Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
• Patient must have had a lapse in growth hormone treatment, **AND**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
• Patient must not have diabetes mellitus, **AND**
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
• Patient must be male and must not have a bone age of 15.5 years or more; **OR**
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

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**Authority required**

**Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants**

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

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**Authority required**

**Biochemical growth hormone deficiency and precocious puberty**

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
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• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**
Hypothalamic-pituitary diseaese secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of \(7.5\text{mg/m}^2/\text{week}\) or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program)* Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program)* Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

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**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.
Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a change in growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Special Arrangement 2015

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic
dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general pediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; and

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Authority required**

**Growth retardation secondary to an intracranial lesion, or cranial irradiation**

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general pediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

- Patient must have had a lapse in growth hormone treatment, AND

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must have been male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have been male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have been female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have been female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
Clinical criteria:
• Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Recommencement of treatment as a reclassified patient
Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have a chronological age of less than 2 years, AND
• Patient must have a documented clinical risk of hypoglycaemia, AND
• Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Recommencement of treatment as a reclassified patient
Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have a chronological age of less than 2 years, AND
• Patient must have a documented clinical risk of hypoglycaemia, AND
• Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 10 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
Patient must have a structural lesion that is not neoplastic; OR
Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
Patient must have hypothalamic obesity, AND
Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
Patient must not have hypothalamic obesity, AND
Patient must not have diabetes mellitus, AND
Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
Patient must not have an active tumour or evidence of tumour growth or activity, AND
Patient must be male and must not have a bone age of 15.5 years or more; OR
Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Treatment criteria:**
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female, OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0 cm, AND
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencing growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed) must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Short stature due to short stature homeobox (SHOX) gene disorders
- Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Short stature due to short stature homeobox (SHOX) gene disorders
- Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
• Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (46X mosaic karyotype with the presence of any Y chromosome mosaic material karyot or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND
• Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6
months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required
Short stature associated with chronic renal insufficiency
Treatment Phase: Recommencement of treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:
- Patient must be aged 3 years or older.
- The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication ‘short stature associated with chronic renal insufficiency’ undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m², prescribers must seek reclassification short stature and slow growth.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.
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Population criteria:
- Patient must be aged 3 years or older.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general pediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

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**SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatement Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
Note: If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

### Authority required

**Growth retardation secondary to an intracranial lesion, or cranial irradiation**

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, \textbf{AND}
- Patient must have had a lapse in growth hormone treatment, \textbf{AND}
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); \textbf{OR}
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; \textbf{OR}
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; \textbf{OR}
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, \textbf{AND}
- Patient must not have diabetes mellitus, \textbf{AND}
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, \textbf{AND}
- Patient must not have an active tumour or evidence of tumour growth or activity, \textbf{AND}
- Patient must be male and must not have a bone age of 15.5 years or more; \textbf{OR}
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; \textbf{OR}
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; \textbf{AND}
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; \textbf{AND}
3. Recent growth data (height and weight); \textbf{AND}
4. A bone age result performed within the last 12 months; \textbf{AND}
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Recommenement of treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a chronological age of 5 years or greater.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Biochemical growth hormone deficiency and precocious puberty
Treatment Phase: Recommenement of treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
• Patient must have had a lapse in growth hormone treatment, AND
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.
continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Recommencement of treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
• Patient must have had a lapse in growth hormone treatment, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).
The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note:** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase:** Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

**Short stature associated with chronic renal insufficiency**

**Treatment Phase: Recommencement of treatment**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication ‘short stature associated with chronic renal insufficiency’ undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

**Short stature and poor body composition due to Prader-Willi syndrome**

**Treatment Phase: Recommencement of treatment**
Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.

Population criteria:
- Patient must not have a chronological age of equal to or greater than 18 years.

Clinical criteria:
- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height, weight, and waist circumference, not older than three months); AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND
Note

If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

**Authority required**

**Short stature and slow growth**

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; **OR**
- Patient must have been male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have been male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of
growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Biological growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.**

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pelliculidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more. The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

**Treatment Phase:** Recomencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

- Patient must have had a lapse in growth hormone treatment, AND

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness, OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness, OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic
dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

- Patient must have a structural lesion that is not neoplastic; OR

- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

- Patient must have hypothalamic obesity, AND

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 and 6 month interval immediately prior to commencement of growth hormone treatment; OR

- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

- Patient must not have diabetes mellitus, AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

- Patient must not have an active tumour or evidence of tumour growth or activity, AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome

**Treatment Phase:** Recommencement of treatment as a reclassified patient

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female, OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0 cm, AND
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to recommencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**

Short stature associated with Turner syndrome
Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Authority required**
Short stature associated with chronic renal insufficiency

**Treatment Phase: Recommencement of treatment as a reclassified patient**

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency. **AND**
- Patient must have had a lapse in growth hormone treatment. **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems.

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be male, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR
• Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

• Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

• Patient must not have diabetes mellitus, AND

• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

• Patient must not have an active tumour or evidence of tumour growth or activity, AND

• Patient must be male and must not have a height greater than or equal to 167.7cm; OR

• Patient must be female and must not have a height greater than or equal to 155.0cm, AND

• Patient must be male and must not have a bone age of 15.5 years or more; OR

• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**
Short stature and poor body composition due to Prader-Willi syndrome

**Treatment Phase:** Recomencement of treatment as a reclassified patient

**Treatment criteria:**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, AND
- Patient must have had a lapse in growth hormone treatment, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness, AND

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, AND
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, AND
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a chronological age of 18 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR
   (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The date that skeletal maturity was achieved (if applicable); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
### SOMATROPIN

**Authority required**

Short stature and slow growth  
Treatment Phase: Continuing treatment  

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**

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<th>No. of Rpts</th>
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<th>MRVSN ($)</th>
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• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more, AND
• Patient must be male and must not have a height greater than or equal to 167.7cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Short stature associated with biochemical growth hormone deficiency
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND
• Patient must not have been on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Note
Any queries concerning the arrangements to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication ‘short stature due to biochemical growth hormone deficiency’.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
Note any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 •

Clinical criteria:

Treatment Phase: Continuing treatment

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND
- Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Short stature associated with Turner syndrome
Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have a bone age of 13.5 years or greater, AND
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Short stature due to short stature homeobox (SHOX) gene disorders

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.5 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Short stature associated with chronic renal insufficiency

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
• Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND
• Patient must not have an eGFR equal to or greater than 30mL/min/1.73m², AND
• Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
• Patient must be female and must not have a height greater than or equal to 155.0 cm, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

Note: Prescribers concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001

Authority required
Short stature and poor body composition due to Prader-Willi syndrome
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, AND
• Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, AND
• Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved waist circumference while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have not been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females), AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity.

Population criteria:
• Patient must not have a chronological age of equal to or greater than 18 years.

Clinical criteria:
• Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Growth Hormone Program

Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins

Reply Paid 9826
HOBART TAS 7001

Authority required
Short stature and slow growth
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; **OR**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Short stature associated with biochemical growth hormone deficiency

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

- Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmaco logical or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmaco logical or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmaco logical or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services
Prior Written Approval of Complex Drugs
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Reply Paid 9826
HOBART TAS 7001

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
Patient must not have an active tumour or evidence of tumour growth or activity, AND
Patient must be male and must not have a bone age of 15.5 years or more; OR
Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
   (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
   (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a
continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a chronological age of less than 2 years, AND
- Patient must have a documented clinical risk of hypoglycaemia, AND
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Biochemical growth hormone deficiency and precocious puberty
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
• Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
• Patient must be female and menarche occurred before the chronological age of 10 years, AND
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
• Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
• Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001

Authority required
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth
Treatment Phase: Continuing treatment as a reclassified patient
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment to be under S100 growth hormone program); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormalities including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of other hypothalamic/pituitary hormone deficiencies (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR
- Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must be male and must not have a bone age of 15.5 years or more; OR
• Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks’ worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Short stature associated with Turner syndrome

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
• Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND
• Patient must not have diabetes mellitus, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a bone age of 2.5 years or less, AND
• Patient must not have a bone age of 13.5 years or greater, AND
• Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
• Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Short stature due to short stature homebox (SHOX) gene disorders
Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
• Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homebox (SHOX) gene disorders, AND
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient’s increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Short stature associated with chronic renal insufficiency

**Treatment Phase: Continuing treatment as a reclassified patient**

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; **OR**
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; **AND**
- Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; **AND**
- Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 6cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; **OR**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
Treatment criteria:
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
   (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m²; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note: If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30ml/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

Note: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:
- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, AND
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

Growth Hormone Program 1557
continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND
• Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females); AND
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females); AND
• Patient must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females); AND
• Patient must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females); AND
• Patient must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
• Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females); AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
• Patient must not have an active tumour or evidence of tumour growth or activity, AND
• Patient must not have a chronological age of 18 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR
   (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment have been addressed, AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The date that skeletal maturity was achieved (if applicable); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed); Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>somatropin 4.2 units (1.4 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</th>
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<tr>
<td>Genotropin MiniQuick [PF]</td>
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<tr>
<td>Max Qty Packs</td>
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<th>Brand Name and Manufacturer</th>
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<th>Brand Name and Manufacturer</th>
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<th>Brand Name and Manufacturer</th>
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<th>somatropin 1.8 units (600 microgram) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</th>
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IVF Treatment Program

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GENITO URINARY SYSTEM AND SEX HORMONES

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

PROGESTOGENS

Pregnen (4) derivatives

PROGESTERONE

Authority required (STREAMLINED)
4997
Assisted Reproductive Technology

Clinical criteria:
- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, AND
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 200 mg capsule, 42
10930G
Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | .. | .. | 86.68 | 38.80 | Utrogestan [HB]

progesterone 100 mg pessary, 21
10116K
Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
2 | .. | .. | *104.99 | 38.80 | Endometrin [FP]

progesterone 200 mg pessary, 15
9609R
Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
3 | .. | .. | *171.94 | 38.80 | Oripro [ON]

progesterone 100 mg pessary, 15
9608Q
Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
3 | .. | .. | *156.55 | 38.80 | Oripro [ON]

PROGESTERONE

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
5045
Assisted Reproductive Technology

Clinical criteria:
- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, AND
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 8% vaginal gel, 15 applications
6366C
Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
2 | .. | .. | *300.59 | 38.80 | Crinone 8% [SG]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

CHORIOGONADOTROPIN ALFA

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
5019
Assisted Reproductive Technology

Clinical criteria:
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 dose
6182J
Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | .. | .. | 63.21 | 38.80 | Ovidrel [SG]
GENITO URINARY SYSTEM AND SEX HORMONES

- **CORIFOLLITROPIN ALFA**
  - Authority required (STREAMLINED)
  - 5009
  - Assisted Reproductive Technology
  - **Clinical criteria:**
    - The treatment must be for controlled ovarian stimulation, AND
    - Patient must have an antral follicle count of 20 or less, AND
    - Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule, AND
    - Patient must be undergoing a gonadotrophin releasing antagonist cycle.

  - **Corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe**
    - 5817E
    - Assisted Reproductive Technology
    - **Clinical criteria:**
      - Patient must have an antral follicle count of 20 or less,
      - Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule,
      - Patient must be undergoing a gonadotrophin releasing antagonist cycle.

  - **Corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**
    - 5816D
    - Assisted Reproductive Technology

  - **FOLLITROPIN ALFA**
  - Authority required (STREAMLINED)
  - 5027
  - Assisted Reproductive Technology
  - **Clinical criteria:**
    - Patient must be undergoing a gonadotrophin releasing antagonist cycle.

  - **Follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge**
    - 6433N
    - Assisted Reproductive Technology

  - **Follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices**
    - 10861P
    - Assisted Reproductive Technology

  - **Follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge**
    - 6431L
    - Assisted Reproductive Technology

  - **Follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices**
    - 10872F
    - Assisted Reproductive Technology

  - **Follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices**
    - 10867Y
    - Assisted Reproductive Technology

  - **Follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge**
    - 6432M
    - Assisted Reproductive Technology

  - **Follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices**
    - 10873G
    - Assisted Reproductive Technology

  - **Follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices**
    - 10866X
    - Assisted Reproductive Technology

- **FOLLITROPIN ALFA + LUTROPIN ALFA**
  - Authority required (STREAMLINED)
  - 5250
  - Stimulation of follicular development
  - **Clinical criteria:**
    - Patient must have severe LH deficiency, AND

  - **Follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices**
    - 10872F
    - Assisted Reproductive Technology

  - **Follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices**
    - 10867Y
    - Assisted Reproductive Technology

  - **Follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge**
    - 6432M
    - Assisted Reproductive Technology

  - **Follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices**
    - 10873G
    - Assisted Reproductive Technology

  - **Follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices**
    - 10866X
    - Assisted Reproductive Technology
• Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment, **AND**
• Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**FOLLITROPIN ALFA**

10491E

<table>
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<th>Max.Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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**FOLLITROPIN BETA**

**Authority required (STREAMLINED)**

5027

Assisted Reproductive Technology

**Clinical criteria:**

• Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

6464F

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**follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge**

6335K

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<td>Puregon 300 IU/0.36 mL [MK]</td>
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**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

6336L

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<td>38.80</td>
<td></td>
<td>Puregon 600 IU/0.72 mL [MK]</td>
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</table>

**HUMAN CHORIONIC GONADOTROPHIN**

**Authority required (STREAMLINED)**

6991

Assisted Reproductive Technology

**Clinical criteria:**

• Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack**

11156E

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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

11154C

<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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**HUMAN MENOPAUSAL GONADOTROPHIN**

**Authority required (STREAMLINED)**

5027

Assisted Reproductive Technology

**Clinical criteria:**

• Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**human menopausal gonadotrophin 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

2036E

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<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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**human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack**

2038G

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**LUTROPIN ALFA**

**Authority required (STREAMLINED)**

5251

Stimulation of follicular development

**Clinical criteria:**
• Patient must have severe LH deficiency, AND
• Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**lutropin alfa 75 units injection [1 vial] & inert substance diluent [1 mL vial], 1 pack**

<table>
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<th>Max Qty</th>
<th>Packs</th>
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**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**HYPOTHALAMIC HORMONES**

**Gonadotropin-releasing hormones**

**NAFARELIN**

*Authority required (STREAMLINED)*

*5046*

**Assisted Reproductive Technology**

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, AND
- Patient must be undergoing controlled ovarian stimulation, AND
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

<table>
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<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<td>*227.63</td>
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<td>Synarel [PF]</td>
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**Anti-gonadotropin-releasing hormones**

**CETRORELIX**

*Authority required (STREAMLINED)*

*5046*

**Assisted Reproductive Technology**

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, AND
- Patient must be undergoing controlled ovarian stimulation, AND
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**cetrorelix 250 microgram injection [1 vial] & inert substance diluent [1 mL syringe], 1 pack**

<table>
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<th>Packs</th>
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<td>*462.45</td>
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**GANIRELIX**

*Authority required (STREAMLINED)*

*5046*

**Assisted Reproductive Technology**

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, AND
- Patient must be undergoing controlled ovarian stimulation, AND
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe**

<table>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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**ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

<table>
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<th>Max Qty</th>
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<th>No. of Rpts</th>
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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**ENDOCRINE THERAPY**

**HORMONES AND RELATED AGENTS**

**Gonadotropin releasing hormone analogues**
• TRIPTORELIN

**Authority required (STREAMLINED)**

5046

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**Triptorelin acetate 100 microgram/mL injection, 7 x 1 mL syringes**

<table>
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<th>10907C</th>
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<td>*216.59</td>
<td>38.80</td>
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<td>Decapeptyl [FP]</td>
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</table>
## NERVOUS SYSTEM

### OTHER NERVOUS SYSTEM DRUGS

#### DRUGS USED IN ADDICTIVE DISORDERS

**Drugs used in opioid dependence**

#### BUPRENORPHINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

**Opiate dependence**

**Treatment Phase:** Maintenance and detoxification (withdrawal)

**Clinical criteria:**
- The treatment must be within a framework of medical, social and psychological treatment.

**buprenorphine 2 mg sublingual tablet, 7**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>Price ex manufacturer $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.98</td>
<td>Subutex [IR]</td>
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</table>

**buprenorphine 400 microgram sublingual tablet, 7**

<table>
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<tr>
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</table>

**buprenorphine 8 mg tablet, 7**

<table>
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<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>1</td>
<td>28.60</td>
<td>Subutex [IR]</td>
</tr>
</tbody>
</table>

#### BUPRENORPHINE + NALOXONE

**Note** Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

**Opiate dependence**

**Clinical criteria:**
- The treatment must be within a framework of medical, social and psychological treatment.

**buprenorphine 8 mg + naloxone 2 mg sublingual film, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</tr>
</thead>
<tbody>
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</table>

**buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28**

<table>
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</table>

#### METHADONE

**Caution** The risk of drug dependence is high.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

**Opiate dependence**
### NERVOUS SYSTEM

**methadone hydrochloride 5 mg/mL oral liquid, 1 L**

<table>
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<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<td>&quot;Biodone Forte [MW]&quot;</td>
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**methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

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</thead>
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<td>7.91</td>
<td>&quot;Aspen Methadone Syrup [QA]&quot;</td>
<td>&quot;Biodone Forte [MW]&quot;</td>
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Repatriation Pharmaceutical Benefits Scheme

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card
This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

White card
A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:
- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

Orange card
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:
- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.

For more information go to the Department of Veterans' Affairs website: http://www.dva.gov.au
RPBS Explanatory Notes

Introduction

The Australian Repatriation System
- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the Veterans’ Entitlements Act 1986 the Department of Veterans’ Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions
- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the Schedule of Pharmaceutical Benefits book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient’s full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements
- The prior approval of the Department is required to prescribe the following:
  - ‘Authority required’ items (excluding ‘Authority required (STREAMLINED)’ items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the National Health Act 1953; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the Schedule of Pharmaceutical Benefits (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)

All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
- using the Department’s national free call number 1800 552 580; or
- by mailing the written authority prescription to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
- A current clinical report on the patient’s condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
- Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
- Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
- When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
- Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
- For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans’ Affairs for payment.

Palliative Care Drugs
- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam
  - cyclizine
  - dexamethasone
Miscellaneous Pricing Rules

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoice, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer’s original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer’s original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.

For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

- Under Department of Veterans’ Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO’s private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

- Optometrists approved as ‘PBS prescribers’ may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe ‘Authority required’ optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be priced on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be priced on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the Schedule of Pharmaceutical Benefits.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used is used shall be endorsed on the prescription form.

Repatriation Pharmaceutical Benefits Scheme
• The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
• For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight
• Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals
• For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
• The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges
• Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions
• The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing
• Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters "TPX" at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

Contact the Department of Veterans' Affairs

Authority Prescription Applications
Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:
REPLY PAID 9998
VAPAC (Veterans’ Affairs Pharmaceutical Advisory Centre)
Department of Veterans’ Affairs
GPO Box 9998
BRISBANE QLD 4001
For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580
Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.
Wound Assessment and Dressing Identification

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound’s healing process should be undertaken.

DRESSINGS

Pink Epithelialising Wound
Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

<table>
<thead>
<tr>
<th>Covering</th>
<th>Absorbing</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Film; Film Island</td>
<td>o Foam (Light Exudate); Hydroactive (Superficial Wound—Light Exudate)</td>
</tr>
<tr>
<td>o Gauze—Paraffin; Non-adherent</td>
<td>o Hydrocolloid (Superficial Wound—Light Exudate)</td>
</tr>
</tbody>
</table>

Red Granulating Wound
Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

<table>
<thead>
<tr>
<th>LIGHT EXUDATE: Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(A) Absorbing</strong></td>
<td>o Foam (Light Exudate); Hydroactive (Superficial Wound—Light Exudate); Hydrocolloid (Superficial Wound—Light Exudate)</td>
</tr>
<tr>
<td><strong>(B) Moisture donating</strong></td>
<td>o Hydrogel—Amorphous; Hydrogel—Sheet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HIGH EXUDATE: Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(A) Absorbing</strong></td>
<td>o Alginate (Superficial Wound); Foam—Heavy Exudate; Hydroactive (Superficial Wound—Moderate Exudate); Hydrocolloid (Superficial Wound—Moderate/High Exudate)</td>
</tr>
<tr>
<td><strong>(B) Moisture donating</strong></td>
<td>NOT APPROPRIATE</td>
</tr>
</tbody>
</table>

Yellow Sloughy Wound
Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

<table>
<thead>
<tr>
<th>LIGHT EXUDATE: Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(A) Absorbing</strong></td>
<td>o Cadexomer Iodine; Foam—Light Exudate; Foam with Charcoal; Hydroactive (Superficial Wound—Moderate Exudate); Hydrocolloid (Superficial Wound—Moderate/High Exudate)</td>
</tr>
<tr>
<td><strong>(B) Moisture Donating</strong></td>
<td>o Hydrogel—Amorphous; Hydrogel—Sheet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HIGH EXUDATE: Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(A) Absorbing</strong></td>
<td>o Alginate (Superficial Wound); Cadexomer Iodine; Foam—Heavy Exudate; Hydroactive (Superficial Wound—Moderate/High Exudate); Hydrocolloid (Superficial Wound—Moderate/High Exudate)</td>
</tr>
<tr>
<td><strong>(B) Moisture donating</strong></td>
<td>NOT APPROPRIATE</td>
</tr>
</tbody>
</table>
**Black Necrotic Wound**

Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

<table>
<thead>
<tr>
<th>DRY / LIGHT EXUDATE:</th>
<th>Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Absorbing</td>
<td>o Hydroactive (Superficial Wound—Light Exudate); o Hydrocolloid (Superficial Wound—Light/Moderate Exudate)</td>
<td>o Hydrocolloid (Cavity Wound)</td>
</tr>
<tr>
<td>(B) Moisture donating</td>
<td>o Hydrogel—Amorphous; o Hydrogel—Sheet</td>
<td>o Hydrogel—Amorphous; o Hydrogel—Sheet</td>
</tr>
</tbody>
</table>

**Infected Wounds**

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

**Malodorous Wounds**

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

**Minor Skin Trauma**

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

**Ordering Products**

**Ordering Coloplast Products**

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**Ordering Hartmann Products**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**Ordering Molnlycke Healthcare Products**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**Ordering Smith & Nephew Products**

Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.
ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

DRUGS FOR ACID RELATED DISORDERS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

DRUGS FOR CONSTIPATION

ANTACIDS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

DRUGS FOR CONSTIPATION

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

ELECTROLYTES WITH CARBOHYDRATES

ANTIPOPSULSIVES

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

VITAMINS

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

VITAMIN B-COMPLEX, INCL. COMBINATIONS

MINERAL SUPPLEMENTS

CALCIUM

BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

ANTIANEMIC PREPARATIONS

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

IRRIGATING SOLUTIONS

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

EMOLLIENTS AND PROTECTIVES

EMOLLIENTS AND PROTECTIVES

PROTECTIVES AGAINST UV-RADIATION

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

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<td>ANTIHISTAMINES FOR SYSTEMIC USE</td>
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<td>DECONGESTANTS AND ANTIALLERGICS</td>
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<td>OTHER NUTRIENTS</td>
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</tr>
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</table>
ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE

chlorhexidine gluconate 0.2% mouthwash, 300 mL

4204G

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>‡1</td>
<td></td>
<td>18.79</td>
<td>6.30</td>
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<td>Savacol Mouth and Throat Rinse [OM]</td>
</tr>
</tbody>
</table>

chlorhexidine gluconate 0.2% mouthwash, 250 mL

4161B

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>‡1</td>
<td></td>
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<td>6.30</td>
<td></td>
<td>Plaqacide [OB]</td>
</tr>
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</table>

NYSTATIN

nystatin 100 000 units/mL oral liquid, 24 mL

10854G

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<th>Premium $</th>
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<tr>
<td>‡1</td>
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<td>6.30</td>
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<td>Pharmacy Action Nystatin Oral Drops [GQ]</td>
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<tr>
<td></td>
<td></td>
<td>18.81</td>
<td>6.30</td>
<td>*</td>
<td>Mycostatin Oral Drops [QA]</td>
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DRUGS FOR ACID RELATED DISORDERS

ANTACIDS

Calcium compounds

CALCIUM CARBONATE + GLYCINE

Note For patients with chronic renal failure.
calcium carbonate 420 mg + glycine 180 mg chewable tablet, 100

4055K

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<td>2</td>
<td>5</td>
<td>*25.67</td>
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<td>Titralac [MM]</td>
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Combinations and complexes of aluminium, calcium and magnesium compounds

ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE

ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1

4118R

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<td>5</td>
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<td>Mylanta Double Strength [JT]</td>
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DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE

mebeverine hydrochloride 135 mg tablet, 90

4328T

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<td>28.91</td>
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<td></td>
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<td>33.41</td>
<td>6.30</td>
<td>*</td>
<td>Colofac [GO]</td>
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BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

hyoscine butylobromide 20 mg/mL injection, 5 x 1 mL ampoules

4279F

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<td>Buscopan [VZ]</td>
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# DRUGS FOR CONSTIPATION

## Softeners, emollients

### DOCUSATE

docusate sodium 50 mg tablet, 100

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### BISACODYL

bisacodyl 10 mg suppository, 10

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<tr>
<td>3</td>
<td>5</td>
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<td>*23.71</td>
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<td>* Petrus Bisacodyl Suppositories [PP]</td>
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<td></td>
<td></td>
<td>..</td>
<td>*25.00</td>
<td>6.30</td>
<td>* Dulcolax [VZ]</td>
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bisacodyl 10 mg suppository, 12

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<tbody>
<tr>
<td>3</td>
<td>4</td>
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<td>*21.43</td>
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<td>Petrus Bisacodyl Suppositories [PP]</td>
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</table>

### DOCUSATE + SENNOSIDE B

docusate sodium 50 mg + sennoside B 8 mg tablet, 90

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<tr>
<td>1</td>
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<td>16.93</td>
<td>6.30</td>
<td>Pharmacy Action Laxative with Senna [GQ]</td>
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docusate sodium 50 mg + sennoside B 8 mg tablet, 100

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### DOCUSATE + SENNOSIDES

docusate sodium 50 mg + sennosides 11.27 mg tablet, 90

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<tbody>
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<td>16.97</td>
<td>6.30</td>
<td>* Chemists’ Own Laxative with Senna [RW]</td>
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<tr>
<td></td>
<td></td>
<td>..</td>
<td>20.02</td>
<td>6.30</td>
<td>* Co-Senna [PP]</td>
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<tr>
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<td>..</td>
<td>20.02</td>
<td>6.30</td>
<td>* Coloxyl with Senna [FM]</td>
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</table>

### SENNOSIDE B

sennoside B 7.5 mg tablet, 100

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<td>16.46</td>
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<td>* Senna-Gen [PP]</td>
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<td>..</td>
<td>17.56</td>
<td>6.30</td>
<td>* Senokot [RC]</td>
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## Bulk-forming laxatives

### DRY PSYLLIUM HUSK
dry psyllium husk 3.5 g powder for oral liquid, 30 sachets

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<tbody>
<tr>
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<td>20.85</td>
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<td>Fybogel [RC]</td>
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### PSYLLIUM HUSK POWDER

#### PSYLLIUM HYDROPHILIC MUCILLOID

Oral powder (orange-flavoured, sugar-free) 283 g, 1

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<tbody>
<tr>
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<td>24.35</td>
<td>6.30</td>
<td>Metamucil Orange Smooth [PY]</td>
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Oral powder (non-flavoured) 336 g, 1

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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>21.18</td>
<td>6.30</td>
<td>Fibre Health Natural Granular [PP]</td>
</tr>
</tbody>
</table>
ALIMENTARY TRACT AND METABOLISM

- **Rhamnus Frangula + Sterculia**
  - *Rhamnus frangula 80 mg/g + Sterculia 620 mg/g granules, 500 g*
  - 4558X

- **Sorbitol + Citric Acid + Lauryl Sulfoacetate Sodium**
  - *Sorbitol 3.125 g/5 mL + Citrate sodium dihydrate 450 mg/5 mL + Lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL*
  - 4462W

- **Glycerol**
  - **Glycerol 1.4 g suppository, 12**
    - 10596Q
  - **Glycerol 700 mg suppository, 12**
    - 10586E
  - **Glycerol 2.8 g suppository, 12**
    - 4246L

- **Antidiarrheals, Intestinal Antiinflammatory/Anti Infective Agents**
  - **Electrolytes with Carbohydrates**
    - **Oral rehydration salt formulations**
  - **Sodium Chloride + Potassium Chloride + Glucose Monohydrate + Citric Acid**
    - *Sodium chloride 470 mg + Potassium chloride 300 mg + Glucose monohydrate 3.56 g + Sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets*
    - 10574M

- **Antipropulsives**
  - **Antipropulsives**
  - **Loperamide**
    - **Loperamide hydrochloride 2 mg capsule, 12**
      - 10592L
    - **Loperamide hydrochloride 2 mg capsule, 20**
      - 11135C

- **Antihypertensive Preparations, Excl. Diet Products**
  - **Peripherally acting antiobesity products**

- **Orlistat**
  - *Note: The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.*
  - **Authority required**
    - **Obesity**
Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities:(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, AND
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), AND
- The treatment must not exceed 12 months in total from initial application, AND
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

Authority required

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must have reduced their initial body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, AND
- The treatment must not exceed 12 months in total from initial application, AND
- Patient must not receive more than 1 continuous treatment in a lifetime, AND
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Authority required

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must have reduced their initial body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, AND
- The treatment must not exceed 12 months in total from initial application, AND
- Patient must not receive more than 1 continuous treatment in a lifetime, AND
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

orlistat 120 mg capsule, 84

<table>
<thead>
<tr>
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<th>DPMQ</th>
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<td>4570M</td>
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<td>132.67</td>
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VITAMINS

VITAMIN B-COMPLEX, INCL. COMBINATIONS

Vitamin B-complex, plain

- FERRIC PYROPHOSPHATE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + LYSINE
  - cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL

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<td>4493L</td>
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<td>2</td>
<td>..</td>
<td>17.11</td>
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</table>
- The condition must be associated with chronic renal failure.

### CALCIUM

**Restricted benefit**
- Hypocalcaemia
- Osteoporosis
- Proven calcium malabsorption

#### CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>DPMO $</th>
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<td>4</td>
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<td>*29.67</td>
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<td>Cal-500 [PP]</td>
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#### CALCIUM Tablet 600 mg (as carbonate), 120

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<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*24.13</td>
<td>6.30</td>
<td>CAL-600 [PP]</td>
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</table>

#### OTHER MINERAL SUPPLEMENTS

**Magnesium**

**MAGNESIUM ASPARTATE DIHYDRATE**

- **Restricted benefit**
- Hypomagnesaemia

The condition must be documented in the patient’s medical records.

#### Magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

<table>
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<td>Mag-Sup [PP]</td>
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<td>Magmin [BB]</td>
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### BLOOD AND BLOOD FORMING ORGANS

### ANTITHROMBOTIC AGENTS

**Platelet aggregation inhibitors excl. heparin**

#### ASPIRIN

aspirin 100 mg tablet, 90

<table>
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<td>Cardiprin 100 [RC]</td>
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aspirin 100 mg tablet, 112

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<td>12.93</td>
<td>6.30</td>
<td></td>
<td>Spren 100 [OW]</td>
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</table>

Note The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.
aspirin 100 mg enteric capsule, 84

<table>
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<td>.</td>
<td>18.22</td>
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<td>Astrix [YN]</td>
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**CLOPIDOGREL**

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Authority required**

For use in patients pre- and post-angioplasty

<table>
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<td>15.18</td>
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<td>* Clopidogrel GH [GQ]</td>
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<td></td>
<td>* Clopidogrel [IB]</td>
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<td>* Clopidogrel AN [EA]</td>
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<td></td>
<td></td>
<td>* Piax [AF]</td>
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<td></td>
<td>* Terry White Chemists</td>
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<td>Clopidogrel [TW]</td>
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**ANTIANEMIC PREPARATIONS**

**IRON PREPARATIONS**

*Iron bivalent, oral preparations*

**FERROUS FUMARATE**

ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60

<table>
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<td>Ferro-tab [AE]</td>
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</table>

Iron in combination with folic acid

**FERROUS FUMARATE + FOLIC ACID**

ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60

<table>
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<td>18.78</td>
<td>6.30</td>
<td>Ferro-f-tab [AE]</td>
</tr>
</tbody>
</table>

**VITAMIN B12 AND FOLIC ACID**

*Vitamin B12 (cyanocobalamin and analogues)*

**HYDROXOCOBALAMIN**

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B₁₂ deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

Pernicious anaemia

**Restricted benefit**

Proven vitamin B12 deficiencies other than pernicious anaemia

**Restricted benefit**

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>.</td>
<td>.</td>
<td>15.36</td>
<td>6.30</td>
<td>* Vita-B12 [GH]</td>
</tr>
</tbody>
</table>

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>.</td>
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<td>15.36</td>
<td>6.30</td>
<td>* Neo-B12 [PF]</td>
</tr>
</tbody>
</table>
Folic acid and derivatives

- **FOLIC ACID**
  - folic acid 500 microgram tablet, 100
    - 10584C
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
    - 2 | .. | *15.15 | 6.30 | * Foltabs 500 [PP]
    - * Megafol 0.5 [AF]

- **FOLIC ACID**
  - Note: The 5 mg strength tablet should be used in malabsorption states only.
  - folic acid 5 mg tablet, 100
    - 10573L
    - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
    - 2 | 1 | *17.37 | 6.30 | Megafol 5 [AF]

- **BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS**
  - **IRRIGATING SOLUTIONS**
    - **Salt solutions**
      - **SODIUM CHLORIDE**
        - sodium chloride 0.9% (9 g/L) solution, 1 L bottle
          - 4461T
          - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
          - ‡1 | 2 | 14.77 | 6.30 | Baxter Healthcare Pty Ltd [BX]
        - sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle
          - 4460R
          - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
          - ‡1 | 2 | 14.49 | 6.30 | Baxter Healthcare Pty Ltd [BX]

- **CARDIOVASCULAR SYSTEM**
  - **VASOPROTECTIVES**
    - **AGENTS FOR TREATMENT OF HEMORRHODS AND ANAL FISSURES FOR TOPICAL USE**
      - **Other agents for treatment of hemorrhoids and anal fissures for topical use**
    - **ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE**
      - zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12
        - 4040P
        - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
        - ‡1 | 1 | .. | 12.85 | 6.30 | Anusol [JT]
      - zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g
        - 4039N
        - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
        - ‡1 | 1 | .. | 18.06 | 6.30 | Anusol [JT]

- **DERMATOLOGICALS**
  - **ANTIFUNGALS FOR DERMATOLOGICAL USE**
    - **ANTIFUNGALS FOR TOPICAL USE**
      - **Antibiotics**
        - **NYSTATIN**
          - nystatin 100 000 units/g cream, 15 g
            - 4001N
            - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
            - ‡1 | 1 | .. | 16.10 | 6.30 | Mycostatin [FM]
      - **Imidazole and triazole derivatives**
        - **CLOTRIMAZOLE**
          - clotrimazole 1% cream, 20 g
            - 4004R
            - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
            - ‡1 | 1 | .. | 12.85 | 6.30 | * Pharmacy Action Anti-Fungal Cream [GQ]
            - .. | .. | 13.19 | 6.30 | * Clonea [AF]
- **KETOCONAZOLE**
  - **Restricted benefit**
  - Severe seborrhoeic dermatitis

  *KETOCONAZOLE 2% shampoo, 100 mL*

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>ü1</td>
<td>..</td>
<td>22.35</td>
<td>6.30</td>
<td></td>
<td>Sebizole [EA]</td>
</tr>
</tbody>
</table>

- **MICONAZOLE**
  - miconazole nitrate 2% cream, 40 g

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<tr>
<td>ü1</td>
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<td>17.40</td>
<td>6.30</td>
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<td>Resolve Thrush [EO]</td>
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</table>

- **AMOROLFINE**
  - **Restricted benefit**
  - Onychomycosis

  *AMOROLFINE 5% application, 5 mL*

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td></td>
<td></td>
<td>61.08</td>
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<td>Sandoz Nail Repair [SZ]</td>
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<td>67.73</td>
<td>6.30</td>
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<td>Pharmacy Action Anti-Fungal</td>
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<td>83.90</td>
<td>6.30</td>
<td></td>
<td>Aporyl [TX]</td>
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<tr>
<td></td>
<td></td>
<td>92.65</td>
<td>6.30</td>
<td></td>
<td>Loceryl [GA]</td>
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</table>

- **TERBINAFINE**
  - **Restricted benefit**
  - Tinea pedis

  *TERBINAFINE 1% gel, 15 g*

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tr>
<td>ü1</td>
<td>..</td>
<td>25.81</td>
<td>6.30</td>
<td></td>
<td>Lamisil DermGel [GK]</td>
</tr>
</tbody>
</table>

  *TERBINAFINE hydrochloride 1% cream, 15 g*

<table>
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<tbody>
<tr>
<td>ü1</td>
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<td>24.54</td>
<td>6.30</td>
<td></td>
<td>Lamisil [GK]</td>
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</tbody>
</table>

- **TOLNAFTATE**
  - tolnaftate 0.07% spray, 100 g

<table>
<thead>
<tr>
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<tr>
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<td>Tinaderm [BN]</td>
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</table>

**ANTIFUNGALS FOR SYSTEMIC USE**

**Antifungals for systemic use**

- **TERBINAFINE**
  - **Authority required**
  - Onychomycosis

  **Clinical criteria:**
  - The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider, OR
  - The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

  *TERBINAFINE 250 mg tablet, 42*

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>GenRx Terbinafine [GX]</td>
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<td>Tamsil [RW]</td>
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<td></td>
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<td>Terbinafine Sandoz [SZ]</td>
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<td></td>
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<td>Lamil (Novartis Pharmaceuticals Australia Pty Limited) [NV]</td>
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<td>Terbinafine GH [GQ]</td>
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<td></td>
<td>Terbinafine Sandoz [SZ]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tinasil [AF]</td>
</tr>
</tbody>
</table>
### EMOLLIENTS AND PROTECTIVES

#### Silicone products

**DIMETHICONE-350 + GLYCEROL**

Restricted benefit
For colostomy and ileostomy use
Restricted benefit
For use by paraplegic and quadriplegic patients
Restricted benefit
For use with surgical appliances

**dimethicone-350 15% + glycerol 2% cream, 500 g**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>4551M</td>
<td>.</td>
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<td>28.47</td>
<td>6.30</td>
<td></td>
<td>Silic 15 [EO]</td>
</tr>
</tbody>
</table>

**dimethicone-350 15% + glycerol 2% cream, 75 g**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>6.30</td>
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<td>Silic 15 [EO]</td>
</tr>
</tbody>
</table>

#### Soft paraffin and fat products

**WOOL ALCOHOLS**

wool alcohols 6% ointment, 100 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>4041Q</td>
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<td>1</td>
<td>17.84</td>
<td>6.30</td>
<td></td>
<td>Eucerin [BE]</td>
</tr>
</tbody>
</table>

#### Carbamide products

**UREA**

urea 10% cream, 100 g

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>4042R</td>
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<td>2</td>
<td>16.11</td>
<td>6.30</td>
<td></td>
<td>Aquacare H.P. [AG]</td>
</tr>
</tbody>
</table>

Other emollients and protectives

**CARMELLOSE SODIUM + GELATIN + PECTIN**

carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% oromucosal paste, 5 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>4518T</td>
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<td>.</td>
<td>15.81</td>
<td>6.30</td>
<td></td>
<td>Orabase [QA]</td>
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</table>

#### SKIN EMOLLIENT

**SKIN EMOLLIENT Bath oil 500 mL, 1**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4122Y</td>
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<td>2</td>
<td>20.59</td>
<td>6.30</td>
<td></td>
<td>Alpha Keri Bath Oil [MT]</td>
</tr>
</tbody>
</table>

**SKIN EMOLLIENT Lotion 500 mL, 1**

<table>
<thead>
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<th>Code</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>Alpha Keri Lotion [MT]</td>
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### PROTECTIVES AGAINST UV-RADIATION

**SUNSCREENS**

SUNSCREENS Lotion (non-alcoholic) 125 mL, 1

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
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<td>Aquasun Lotion SPF 18 [PF]</td>
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</table>

### DERMATOLOGICALS
SUNSCREENS Cream 75 g, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>21.20</td>
<td>6.30</td>
<td>Sunsense Sensitive SPF 50+ [EO]</td>
</tr>
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</table>

**ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.**

Anesthetics for topical use

**LIGNOCaine**

lignocaine hydrochloride anhydrous 2% oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>103.21</td>
<td>6.30</td>
<td></td>
<td>Xylocaine Viscous [QA]</td>
</tr>
</tbody>
</table>

Other antipruritics

**PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE**

Note: For patients who have failed to respond to simple moisturising agents.

PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>‡1</td>
<td>2</td>
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<td>25.44</td>
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<td>Pinetarsol [EO]</td>
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</tbody>
</table>

**ANTIPSORIATICS**

**TARS**

**COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR**

coil tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<td>‡1</td>
<td>2</td>
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<td>19.44</td>
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**ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE**

**ANTIBIOTICS FOR TOPICAL USE**

Other antibiotics for topical use

**MUPIROCIN**

Restricted benefit

Secondarily infected traumatic skin lesions

mupirocin 2% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>20.51</td>
<td>6.30</td>
<td></td>
<td>Bactroban [GK]</td>
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</tbody>
</table>

mupirocin 2% ointment, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>‡1</td>
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<td>20.51</td>
<td>6.30</td>
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<td>Bactroban [GK]</td>
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</tbody>
</table>

**CHEMOTHERAPEUTICS FOR TOPICAL USE**

**Antivirals**

**PODOPHYLLOTOXIN**

Authority required

Ano-genital warts

podophyllotoxin 0.15% cream, 5 g

<table>
<thead>
<tr>
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<tbody>
<tr>
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<td>Wartec Cream [GK]</td>
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</tbody>
</table>

Other chemotherapeutics

**INGENOL MEBUTATE**

Authority required

Solar keratosis

Clinical criteria:
- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

**INGENOL MEButATE**

**Authority required**

**Solar (actinic) keratosis**

**Clinical criteria:**

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

<table>
<thead>
<tr>
<th>RPBS</th>
<th>Max Qty</th>
<th>No of Rpts</th>
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<td>.</td>
<td>Picato [LO]</td>
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**INGENOL MEButATE**

**Authority required**

**Clinical criteria:**

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

<table>
<thead>
<tr>
<th>RPBS</th>
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<td>Picato [LO]</td>
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**CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS**

**CORTICOSTEROIDS, PLAIN**

**Corticosteroids, weak (group I)**

**HYDROCORTISONE ACETATE**

**Restricted benefit**

Corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>RPBS</th>
<th>Max Qty</th>
<th>No of Rpts</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
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<td>.</td>
<td>Cortic-DS 1% [QA]</td>
</tr>
</tbody>
</table>

**Corticosteroids, potent (group III)**

**BETAMETHASONE VALERATE**

**betamethasone (as valerate) 0.1% cream, 30 g**

<table>
<thead>
<tr>
<th>RPBS</th>
<th>Max Qty</th>
<th>No of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4131K</td>
<td>.</td>
<td>2</td>
<td>25.01</td>
<td>6.30</td>
<td>.</td>
<td>Betnovate [QA]</td>
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</tbody>
</table>

**betamethasone (as valerate) 0.1% ointment, 30 g**

<table>
<thead>
<tr>
<th>RPBS</th>
<th>Max Qty</th>
<th>No of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>4132L</td>
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<td>2</td>
<td>25.01</td>
<td>6.30</td>
<td>.</td>
<td>Betnovate [QA]</td>
</tr>
</tbody>
</table>

**MOMETASONE**

**Note** Application to large areas of skin for longer than four weeks is not recommended.

**mometasone furoate 0.1% cream, 50 g**

<table>
<thead>
<tr>
<th>RPBS</th>
<th>Max Qty</th>
<th>No of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4342M</td>
<td>.</td>
<td>.</td>
<td>34.62</td>
<td>6.30</td>
<td>.</td>
<td>Elocon [MK]</td>
</tr>
</tbody>
</table>

**mometasone furoate 0.1% ointment, 50 g**

<table>
<thead>
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<th>No of Rpts</th>
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<th>DPMQ ($)</th>
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<th>Brand Name and Manufacturer</th>
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<td>34.62</td>
<td>6.30</td>
<td>.</td>
<td>Elocon [MK]</td>
</tr>
</tbody>
</table>

**ANTISEPTICS AND DISINFECTANTS**

**ANTISEPTICS AND DISINFECTANTS**

**Iodine products**

**POVIDONE-IODINE**

**povidone-iodine 10% solution, 100 mL**

<table>
<thead>
<tr>
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<th>Max Qty</th>
<th>No of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4411E</td>
<td>.</td>
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<td>24.73</td>
<td>6.30</td>
<td>.</td>
<td>Betadine Antiseptic Liquid [SW]</td>
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</tbody>
</table>
### OTHER DERMATOLOGICAL PREPARATIONS

#### Medicated shampoos

**COAL TAR SOLUTION + TAR + SALICYLIC ACID**

Coal tar solution 1% + tar 1% + salicylic acid 2% solution, 250 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>21.89</td>
<td>6.30</td>
<td></td>
<td>Sebitar [EO]</td>
</tr>
</tbody>
</table>

**SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS**

Salicylic acid with Coal Tar Solution Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>23.23</td>
<td>6.30</td>
<td></td>
<td>Ionil-T [GA]</td>
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**SELENIUM SULFIDE**

Selenium sulfide 2.5% shampoo, 125 mL

<table>
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<td>17.80</td>
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<td>Selsun [DQ]</td>
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</tbody>
</table>

**TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR**

Tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>..</td>
<td>26.50</td>
<td>6.30</td>
<td></td>
<td>Polytar [GK]</td>
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### Wart and anti-corn preparations

**SALICYLIC ACID + LACTIC ACID**

Salicylic acid 16.7% + lactic acid 16.7% application, 15 mL

<table>
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<tr>
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<th>No. of Rpts</th>
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<tbody>
<tr>
<td>‡1</td>
<td>3</td>
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<td>58.15</td>
<td>6.30</td>
<td></td>
<td>Solaraze 3% Gel [FK]</td>
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</table>

### Other dermatologicals

**DICLOFENAC**

Note: Maximum quantity of four tubes (original + 3 repeats) in 12 months.

**Authority required**

- Solar (actinic) keratosis
- Treatment Phase: Management

**Clinical criteria:**

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

Diclofenac sodium 3%, 25 g

<table>
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<th>No. of Rpts</th>
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<tr>
<td>‡1</td>
<td>3</td>
<td>..</td>
<td>58.15</td>
<td>6.30</td>
<td></td>
<td>Solaraze 3% Gel [FK]</td>
</tr>
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</table>

**ICHTHAMMOL**

Note: For patients who have failed to respond to simple moisturising agents.

Ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>..</td>
<td>21.25</td>
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<td>Egoderm Cream [EO]</td>
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</table>

**ICHTHAMMOL + ZINC OXIDE**

Note: For patients who have failed to respond to simple moisturising agents.

Ichthammol 1% + zinc oxide 15% ointment, 50 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>‡1</td>
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<td>..</td>
<td>21.25</td>
<td>6.30</td>
<td></td>
<td>Egoderm Ointment [EO]</td>
</tr>
</tbody>
</table>
IMIQUIMOD

Authority required
Superficial basal cell carcinoma
Treatment Phase: Primary treatment
Clinical criteria:
• The condition must be confirmed by a histological diagnosis, AND
• The condition must be one where other standard treatments are inappropriate, AND
• The condition must require topical drug therapy.

imiquimod 5% cream, 12 x 250 mg sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>86.62</td>
<td>6.30</td>
<td>* Aldiq [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>88.90</td>
<td>6.30</td>
<td>* Aldara [IA]</td>
</tr>
</tbody>
</table>

IMIQUIMOD

Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required
Solar keratosis
Clinical criteria:
• Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

imiquimod 5% cream, 2 x 2 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>91.17</td>
<td>6.30</td>
<td>* Aldara Pump [IA]</td>
</tr>
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</table>

imiquimod 5% cream, 12 x 250 mg sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>86.62</td>
<td>6.30</td>
<td>* Aldiq [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>88.90</td>
<td>6.30</td>
<td>* Aldara [IA]</td>
</tr>
</tbody>
</table>

LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>23.54</td>
<td>6.30</td>
<td>Hamilton Skin Therapy Wash [KY]</td>
</tr>
</tbody>
</table>

PANTHENOL

Note To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

panthenol conditioner, 200 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.90</td>
<td>6.30</td>
<td>SebiRinse [EO]</td>
</tr>
</tbody>
</table>

ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + PURIFIED TALC

zinc oxide 25% + maize starch 55.85% + chlorphenesin 1% + purified talc 18.07% dusting powder, 100 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>16.16</td>
<td>6.30</td>
<td>Z.S.C. [RW]</td>
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</table>

GENITO URINARY SYSTEM AND SEX HORMONES

GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

Antibiotics

NYSTATIN

nystatin 20 000 units/g vaginal cream, 75 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>17.50</td>
<td>6.30</td>
<td>Nilstat [QA]</td>
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</tbody>
</table>
### CLOTRIMAZOLE

clotrimazole 1% vaginal cream, 35 g

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<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.41</td>
<td>6.30</td>
<td>* Clonea 6 Day Cream [AF]</td>
<td>* Pharmacy Action FemCream  [GQ]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>18.62</td>
<td>6.30</td>
<td>* APO-Clotrimazole 6 Day Cream [TX]</td>
<td></td>
<td></td>
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</tbody>
</table>


clotrimazole 2% vaginal cream, 20 g

<table>
<thead>
<tr>
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<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>‡1</td>
<td>..</td>
<td>..</td>
<td>18.62</td>
<td>6.30</td>
<td>APO-Clotrimazole 3 Day Cream [TX]</td>
<td>Clonea 3 Day Cream [AF]</td>
</tr>
</tbody>
</table>

### OTHER GYNECOLOGICALS

### ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

cetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
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<td>34.12</td>
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<td>Aci-Jel [CU]</td>
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### UROLOGICALS

**Drugs used in erectile dysfunction**

### ALPROSTADIL

Authority required

Erectile dysfunction

Clinical criteria:
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, AND
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:
- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

alprostadil 10 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*101.14</td>
<td>6.30</td>
<td>Caverject Impulse [PF]</td>
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</table>

alprostadil 20 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>3</td>
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<td>*125.98</td>
<td>6.30</td>
<td>Caverject Impulse [PF]</td>
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</table>

### SILDENAFIL

Authority required

Erectile dysfunction

Clinical criteria:
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, AND
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:
- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

sildenafil 50 mg tablet, 4

<table>
<thead>
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<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>67.04</td>
<td>6.30</td>
<td>* APO-Sildenafil [TX]</td>
<td>* Sildenafil Actavis [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>77.70</td>
<td>6.30</td>
<td>* Vasaflit 50 [RW]</td>
<td>* Vedafil [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Viagra [PF]</td>
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</table>
sildenafil 100 mg tablet, 4

<table>
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<td>Sildenafil Actavis [EA]</td>
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<td>Terry White Chemists</td>
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<td>Sildenafil [TW]</td>
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<td>Vedafil [AF]</td>
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<td>5</td>
<td>..</td>
<td>83.14</td>
<td>6.30</td>
<td>Chem mart Sildenafil [CH]</td>
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<td>Sildenafil generichealth [GQ]</td>
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<td>Vasafil 100 [RW]</td>
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sildenafil 25 mg tablet, 4

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>..</td>
<td>55.04</td>
<td>6.30</td>
<td>Sildenafil Actavis [EA]</td>
</tr>
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<td></td>
<td>Vedafil [AF]</td>
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<tr>
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<td>5</td>
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<td>55.05</td>
<td>6.30</td>
<td>APO-Sildenafil [TX]</td>
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<td>Viagra [PF]</td>
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<td>5</td>
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<td>63.42</td>
<td>6.30</td>
<td>Vasafil 25 [RW]</td>
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</tbody>
</table>

TADALAFIL

Authority required

Erectile dysfunction

Clinical criteria:
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, AND
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:
- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

tadalafil 20 mg tablet, 4

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>103.85</td>
<td>6.30</td>
<td>Cialis [LY]</td>
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tadalafil 10 mg tablet, 4

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<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>103.85</td>
<td>6.30</td>
<td>Cialis [LY]</td>
</tr>
</tbody>
</table>

VARDENAFIL

Authority required

Erectile dysfunction

Clinical criteria:
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, AND
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:
- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

vardenafil 10 mg tablet, 4

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>71.43</td>
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<td>Levitra [BN]</td>
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vardenafil 20 mg tablet, 4

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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>81.18</td>
<td>6.30</td>
<td>Levitra [BN]</td>
</tr>
</tbody>
</table>

Other urologicals

BICARBONATE + CITRIC ACID + TARTARIC ACID

Restricted benefit

Urinary symptoms

Clinical criteria:
- The treatment must be for when antibiotic or other therapy alone is inappropriate.

sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
<td>‡1</td>
<td>4</td>
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<td>17.29</td>
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<td>Uracoil [EA]</td>
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<td></td>
<td></td>
<td>Ural Sachets [QA]</td>
</tr>
</tbody>
</table>
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

**ALFUZOSIN**

**Authority required**
Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**alfuzosin hydrochloride 10 mg modified release tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
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<tr>
<td>4277D</td>
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<td>..</td>
<td>62.85</td>
<td>6.30</td>
<td>Xatral SR [SW]</td>
</tr>
</tbody>
</table>

**DUTASTERIDE + TAMSULOSIN**

**Authority required**
Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
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<td>35.14</td>
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**TAMSULOSIN**

**Authority required**
Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**tamsulosin hydrochloride 400 microgram modified release tablet, 30**

<table>
<thead>
<tr>
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<td>4070F</td>
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<td>62.85</td>
<td>6.30</td>
<td>Flomaxtra [LS], Tamsulosin Sandoz SR [SZ]</td>
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</tbody>
</table>

Testosterone-5-alpha reductase inhibitors

**DUTASTERIDE**

**Authority required**
Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**dutasteride 500 microgram capsule, 30**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>10095H</td>
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<td>..</td>
<td>30.93</td>
<td>6.30</td>
<td>Avodart [GK]</td>
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</tbody>
</table>

**FINASTERIDE**

**Authority required**
Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**finasteride 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
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<td>75.88</td>
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<td>93.73</td>
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<td>..</td>
<td>98.08</td>
<td>6.30</td>
<td>* Finnacar [RW]</td>
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<td></td>
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<td>..</td>
<td></td>
<td></td>
<td>* APO-Finasteride [TX]</td>
</tr>
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<td></td>
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<td>..</td>
<td></td>
<td></td>
<td>* Finasteride Alphapharm [AF]</td>
</tr>
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<td></td>
<td>..</td>
<td></td>
<td></td>
<td>* Pharmacor Finasteride 5 [CR]</td>
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<tr>
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<td>* Finasteride AN [EA]</td>
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<td></td>
<td></td>
<td>* Finide [AL]</td>
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<tr>
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<td></td>
<td>..</td>
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<td>* Finidex [AL]</td>
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<td>..</td>
<td></td>
<td></td>
<td>* Finasta [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td></td>
<td></td>
<td>* Finasteride-GA 5 [GN]</td>
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<tr>
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<td></td>
<td>..</td>
<td></td>
<td></td>
<td>* Proscar [MK]</td>
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</table>
ANTIINFECTIVES FOR SYSTEMIC USE

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections

azithromycin 500 mg tablet, 3

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

FLUOROURACIL

fluorouracil 5% cream, 20 g

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Tumor necrosis factor alpha (TNF-) inhibitors

INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998
Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans’ Affairs
GPO Box 9998
BRISBANE QLD 4001

Authority required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;
(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
(3) No history of active tuberculosis requiring treatment in the last 3 years;
(4) No history of opportunistic infection in the last 2 months;
(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

Authority required
Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

(1) There is improvement in ESR and/or CRP; and
(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy. Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

infliximab 100 mg injection, 1 vial

<table>
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<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>569.47</td>
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<td>Remicade [JC]</td>
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**MUSCULO-SKELETAL SYSTEM**

**TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN**

**Preparations with salicylic acid derivatives**

**EUCALYPTUS OIL + MENTHOL + METHYL SALICYLATE**
eucalyptus oil 10% + menthol 4% + methyl salicylate 25% cream, 100 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>17.70</td>
<td>6.30</td>
<td>Gold Cross [Bl]</td>
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</table>

**METHYL SALICYLATE**
methyl salicylate 25% liniment, 100 mL

<table>
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<td>1</td>
<td>14.15</td>
<td>6.30</td>
<td>Gold Cross [Bl]</td>
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</table>

methyl salicylate 50% ointment, 100 g

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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**DRUGS FOR TREATMENT OF BONE DISEASES**

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

**Bisphosphonates**

**RISEDRONATE**

Authority required
Preservation of bone mineral density
Clinical criteria:
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

risedronate sodium 35 mg tablet, 4

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>DPMQ $</th>
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<tbody>
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<td>5</td>
<td>35.10</td>
<td>6.30</td>
<td>* Acris Once-a-Week [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Risedronate AN [EA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Risedronate Sandoz [SZ]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>* APO-Risedronate [TX]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>* Risedronate-GA [GN]</td>
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<td></td>
<td></td>
<td></td>
<td>* Risedro once a week [RW]</td>
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risedronate sodium 5 mg tablet, 28

<table>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>35.10</td>
<td>6.30</td>
<td>Actonel [UA]</td>
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</tbody>
</table>

RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>35.10</td>
<td>6.30</td>
<td>Actonel EC [UA]</td>
</tr>
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</table>

Bisphosphonates, combinations
MUSCULO-SKELETAL SYSTEM

### Aelfastronate + Colecalciferol

**Authority required**
Preservation of bone mineral density

**Clinical criteria:**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

#### alendronate 70 mg + colecalciferol 70 microgram tablet, 4 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tr>
<td>2194L</td>
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<td>6.30</td>
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<td>Alendronate plus D3-RDLA [RZ]</td>
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<td></td>
<td>1</td>
<td>20.20</td>
<td>6.30</td>
<td></td>
<td>Chem mart Alendronate Plus D3 70 mg/70 mcg [CH]</td>
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<td></td>
<td></td>
<td>Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW]</td>
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#### alendronate 70 mg + colecalciferol 140 microgram tablet, 4 pack

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<td>Alendronate plus D3-RDLA [RZ]</td>
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<td></td>
<td>1</td>
<td>20.20</td>
<td>6.30</td>
<td></td>
<td>Chem mart Alendronate Plus D3 70 mg/140 mcg [CH]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW]</td>
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</tbody>
</table>

### Aelfastronate + Colecalciferol (&) Calcium Carbonate

**Authority required**
Preservation of bone mineral density

**Clinical criteria:**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

#### alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

<table>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<td>APO-Alendronate Plus D3 and Calcium [MK]</td>
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<td></td>
<td>2</td>
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<td>6.30</td>
<td></td>
<td>Fosamax Plus D-Cal [MK]</td>
</tr>
</tbody>
</table>

### Risedronate (&) Calcium Carbonate

**Authority required**
Preservation of bone mineral density

**Clinical criteria:**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

#### Risedronate Sodium and Calcium Carbonate Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<td></td>
<td>Acron EC Combi [UA]</td>
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#### Risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

<table>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>4059P</td>
<td>1</td>
<td>35.10</td>
<td>6.30</td>
<td></td>
<td>Acris Combi [AF]</td>
</tr>
</tbody>
</table>
**NERVOUS SYSTEM**

**RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**

**Authority required**
Preservation of bone mineral density

**Clinical criteria:**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

**RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL** Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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<tr>
<td>2254P</td>
<td>5</td>
<td>..</td>
<td>35.10</td>
<td>6.30</td>
<td>Actonel EC Combi D [UA]</td>
</tr>
</tbody>
</table>

**NERVOUS SYSTEM**

**ANALGESICS**

**OPIOIDS**

**Natural opium alkaloids**

**MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

**Restricted benefit**
Chronic severe disabling pain

**Clinical criteria:**
- The condition must be unresponsive to non-opioid analgesics.

**MORPHINE sulfate 200 mg modified release tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>4349X</td>
<td>..</td>
<td>..</td>
<td>116.58</td>
<td>6.30</td>
<td>MS Contin [MF]</td>
</tr>
</tbody>
</table>

**Opioids in combination with non-opioid analgesics**

**ASPIRIN + CODEINE**

**aspirin 300 mg + codeine phosphate 8 mg dispersible tablet, 40**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4286N</td>
<td>2</td>
<td>..</td>
<td>17.84</td>
<td>6.30</td>
<td>Aspalgin 40 [QA]</td>
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</tbody>
</table>

**PARACETAMOL + CODEINE**

**paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20**

<table>
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<tr>
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<th>No. of Rpts</th>
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<th>DPMQ</th>
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<tbody>
<tr>
<td>10186D</td>
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<td>13.97</td>
<td>6.30</td>
<td>Pharmacy Action Paracetamol Plus Codeine [GQ]</td>
</tr>
</tbody>
</table>

**paracetamol 500 mg + codeine phosphate 8 mg tablet, 40**

<table>
<thead>
<tr>
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<th>MRVSN</th>
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<td>4275B</td>
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<td>14.80</td>
<td>6.30</td>
<td>Panamax Co. 40 [SW]</td>
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</tbody>
</table>

**OTHER ANALGESICS AND ANTIPYRETICS**

**Anilides**

**PARACETAMOL**

**paracetamol 500 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<th>MRVSN</th>
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<tbody>
<tr>
<td>10582Y</td>
<td>1</td>
<td>12.74</td>
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<td></td>
<td>* APO-Paracetamol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Generic Health Pty Ltd [GQ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Paracetamol (Sandoz) [SZ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Parapane [AF]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Febridol [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Panamax [SW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Paralgin [OW]</td>
</tr>
</tbody>
</table>
paracetamol 240 mg/5 mL oral liquid, 200 mL

<table>
<thead>
<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>10599W</td>
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<td>Panamax 240 Elixir [SW]</td>
</tr>
</tbody>
</table>

**PARACETAMOL**

**Restricted benefit**

Persistent pain

Clinical criteria:
- The condition must be associated with osteoarthritis.

paracetamol 665 mg modified release tablet, 96

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>10598T</td>
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<td>Osteomol 665 Paracetamol</td>
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**PARACETAMOL**

**Restricted benefit**

Chronic arthropathies

paracetamol 500 mg tablet, 100

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<tbody>
<tr>
<td>10585D</td>
<td>3</td>
<td>*16.03</td>
<td>6.30</td>
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</table>

**GABAPENTIN**

**Authority required**

Refractory neuropathic pain

Clinical criteria:
- The condition must be unable to be controlled by other drugs.

gabapentin 400 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>* Gabapentin 400 [CR]</td>
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<td></td>
<td></td>
<td>* Gabapentin GH [QG]</td>
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<td>* GenRx Gabapentin [GX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin 400 [AF]</td>
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</table>

<table>
<thead>
<tr>
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<td></td>
<td></td>
<td></td>
<td>* GenRx Gabapentin [GX]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin Tabs [AF]</td>
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</table>

<table>
<thead>
<tr>
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<td></td>
<td></td>
<td>* Gabapentin 300 [QG]</td>
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<td>* GenRx Gabapentin [GX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin 300 [AF]</td>
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<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Gabapentin Aspen 800 [RW]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Neurontin [PF]</td>
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</table>

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>.</td>
<td>* APO-Gabapentin [TX]</td>
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<table>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4591T</td>
<td>1</td>
<td>15.13</td>
<td>6.30</td>
<td>.</td>
<td>* Gabapentin 100 [AF]</td>
</tr>
</tbody>
</table>

**PSYCHOLEPTICS**

**ANXIOLYTICS**

*Benzodiazepine derivatives*
NERVOUS SYSTEM

**BROMAZEPAM**

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

**Authority required**

**Terminal disease**

**Clinical criteria:**
- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

**Authority required**

**Refractory phobic or anxiety states**

**Clinical criteria:**
- The treatment must be for the short-term.

*bromazepam 3 mg tablet, 30*

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4150K</td>
<td>..</td>
<td>*31.15</td>
<td>6.30</td>
<td></td>
<td>Lexotan [RO]</td>
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</table>

*bromazepam 6 mg tablet, 30*

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>4151L</td>
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<td>*36.89</td>
<td>6.30</td>
<td></td>
<td>Lexotan [RO]</td>
</tr>
</tbody>
</table>

**Azaspirodecanedione derivatives**

**BUSPIRONE**

**Authority required**

**Anxiety**

**Clinical criteria:**
- The treatment must be for the short-term.

*buspirone hydrochloride 5 mg tablet, 50*

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
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<tbody>
<tr>
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<td>38.54</td>
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<td>Buspar [QA]</td>
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</table>

*buspirone hydrochloride 10 mg tablet, 50*

<table>
<thead>
<tr>
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<th>Premium ($)</th>
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<tr>
<td>4145E</td>
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<td>55.01</td>
<td>6.30</td>
<td></td>
<td>Buspar [QA]</td>
</tr>
</tbody>
</table>

**HYPNOTICS AND SEDATIVES**

**Benzodiazepine derivatives**

**FLUNITRAZEPAM**

**Note** This drug should not be used as the first line of treatment.

**Note** Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

**Note** Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

**Authority required**

**Terminal disease**

**Clinical criteria:**
- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

**Authority required**

**Refractory phobic or anxiety states**

**Clinical criteria:**
- The treatment must be for the short-term.

*flunitrazepam 1 mg tablet, 30*

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<td>4216X</td>
<td>..</td>
<td>19.10</td>
<td>6.30</td>
<td></td>
<td>Hypnodorm [AF]</td>
</tr>
</tbody>
</table>

**ZOPICLONE**

**Restricted benefit**

**Insomnia**

**Clinical criteria:**
- The treatment must be for the short-term.
### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

- **Zopiclone 7.5 mg tablet, 30**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 1 | .. | .. | 24.43 | 6.30 |
  - 2 | .. | .. | 27.17 | 6.30 |

- **Mebendazole 100 mg tablet, 6**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 1 | .. | .. | 17.29 | 6.30 |

### OTHER NERVOUS SYSTEM DRUGS

#### DRUGS USED IN ADDICTIVE DISORDERS

**Nicotine**

*Note* Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

**Authority required**

Narcotic dependence

**Clinical criteria:**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

- **Nicotine 14 mg/24 hours patch, 7**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 2 | .. | .. | *54.73 | 6.30 |
  - 2 | .. | .. | *50.97 | 6.30 |

- **Nicotine 5 mg/16 hours patch, 7**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 2 | .. | .. | *54.73 | 6.30 |
  - 2 | .. | .. | *50.97 | 6.30 |

- **Nicotine 15 mg/16 hours patch, 7**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 2 | .. | .. | *54.73 | 6.30 |

- **Nicotine 21 mg/24 hours patch, 7**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 2 | .. | .. | *57.69 | 6.30 |
  - 2 | .. | .. | *67.75 | 6.30 |

- **Nicotine 10 mg/16 hours patch, 7**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 2 | .. | .. | *54.95 | 6.30 |

- **Nicotine 7 mg/24 hours patch, 7**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 2 | .. | .. | *51.57 | 6.30 |

### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

#### ANTHELMINTICS

- **Mebendazole**
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  - 1 | .. | .. | 17.29 | 6.30 |

### RESPIRATORY SYSTEM

#### NASAL PREPARATIONS

**Decongestants and other nasal preparations for topical use**

- **Sympathomimetics, plain**
OXYMETAZOLINE

oxymetazoline hydrochloride 0.05% nasal spray, 15 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>4378K</td>
<td>✱1</td>
<td>..</td>
<td>..</td>
<td>20.42</td>
<td>6.30</td>
<td>Drixine [BN]</td>
</tr>
</tbody>
</table>

oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4379L</td>
<td>✱1</td>
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<td>..</td>
<td>20.08</td>
<td>6.30</td>
<td>Logicin Rapid Relief [QA]</td>
</tr>
</tbody>
</table>

Antiallergic agents, excl. corticosteroids

CROMOGLYCATE

sodium cromoglycate 2% nasal spray, 26 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4468E</td>
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<td>..</td>
<td>25.43</td>
<td>6.30</td>
<td>Rynacrom [SW]</td>
</tr>
</tbody>
</table>

LEVCABASTINE

levocabastine 0.05% nasal spray, 100 actuations

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<td>4311X</td>
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<td>21.37</td>
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<td>Livostin [JT]</td>
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Corticosteroids

BUDESONIDE

Restricted benefit
Severe intractable rhinitis

budesonide 64 microgram/actuation nasal spray, 120 actuations

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4092J</td>
<td>✱1</td>
<td>..</td>
<td>..</td>
<td>41.68</td>
<td>6.30</td>
<td>Budamax Aqueous [PM]</td>
</tr>
</tbody>
</table>

Other nasal preparations

IPRATROPIUM

Restricted benefit
Severe intractable rhinorrhoea

Clinical criteria:
- The condition must be associated with perennial rhinitis, AND
- The condition must be unresponsive to insufflated nasal steroids.

ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4089F</td>
<td>✱1</td>
<td>5</td>
<td>..</td>
<td>26.48</td>
<td>6.30</td>
<td>Aatrovent Nasal Aqueous [VZ]</td>
</tr>
</tbody>
</table>

ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations

<table>
<thead>
<tr>
<th>Code</th>
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<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>4090G</td>
<td>✱1</td>
<td>5</td>
<td>..</td>
<td>32.63</td>
<td>6.30</td>
<td>Aatrovent Nasal Forte [VZ]</td>
</tr>
</tbody>
</table>

NASAL DECONGESTANTS FOR SYSTEMIC USE

Sympathomimetics

PSEUDOEPHEDRINE

g pseudoephedrine hydrochloride 60 mg tablet, 12

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Pts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<tbody>
<tr>
<td>4029C</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.44</td>
<td>6.30</td>
<td>* Pharmacy Action Sinus &amp; Nasal Decongestant Relief [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Logicin Sinus [QA]</td>
</tr>
</tbody>
</table>

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Expectorants
## SENSORY ORGANS

### AMMONIUM + SENEGA ROOT

ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>4</td>
<td>..</td>
<td>13.49</td>
<td>6.30</td>
<td>Gold Cross [BL]</td>
</tr>
</tbody>
</table>

### COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

*Opium alkaloids and derivatives*

### PHOLCODINE

pholcodine 1 mg/mL oral liquid, 100 mL

<table>
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<tr>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>13.35</td>
<td>6.30</td>
<td>Gold Cross [BL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>18.21</td>
<td>6.30</td>
<td>Duro-Tuss [IA]</td>
</tr>
</tbody>
</table>

### ANTIHISTAMINES FOR SYSTEMIC USE

#### Piperazine derivatives

### CETIRIZINE

cetirizine hydrochloride 10 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>28.06</td>
<td>6.30</td>
<td><em>Pharmacy Action Cetrelief [GQ]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>31.29</td>
<td>6.30</td>
<td><em>Alzene [AF]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>34.09</td>
<td>6.30</td>
<td>Zilarex [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>39.81</td>
<td>6.30</td>
<td><em>Zyrtec [JT]</em></td>
</tr>
</tbody>
</table>

*Other antihistamines for systemic use*

### FEXOFENADINE

fexofenadine hydrochloride 60 mg tablet, 20

<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*55.15</td>
<td>6.30</td>
<td>Telfast [SW]</td>
</tr>
</tbody>
</table>

fexofenadine hydrochloride 120 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>27.88</td>
<td>6.30</td>
<td><em>Pharmacy Action Fexorelief 120 [GQ]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>31.09</td>
<td>6.30</td>
<td><em>Xergic [AF]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>35.69</td>
<td>6.30</td>
<td><em>Fexal [SZ]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>47.30</td>
<td>6.30</td>
<td><em>Telfast 120 [SW]</em></td>
</tr>
</tbody>
</table>

### LORATADINE

loratadine 10 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>30.49</td>
<td>6.30</td>
<td><em>Pharmacy Action Lorastyne [GQ]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>34.19</td>
<td>6.30</td>
<td><em>Allerze [AF]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>43.82</td>
<td>6.30</td>
<td><em>Lorano [SZ]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>46.09</td>
<td>6.30</td>
<td><em>Claratyne [BN]</em></td>
</tr>
</tbody>
</table>

### SENSORY ORGANS

#### OPHTHALMOLOGICALS

### DECONGESTANTS AND ANTIALLERGICS

*Sympathomimetics used as decongestants*

### NAPHAZOLINE

naphazoline hydrochloride 0.1% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>18.63</td>
<td>6.30</td>
<td>Albalon Liquifilm [AG]</td>
</tr>
</tbody>
</table>
### NAPHAZOLINE + ANTAZOLINE
Naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>18.38</td>
<td>6.30</td>
<td>Albalon-A [AG]</td>
</tr>
</tbody>
</table>

### LEVOCABASTINE
Levocabastine 0.05% eye drops, 4 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>21.37</td>
<td>6.30</td>
<td>Livostin [JT]</td>
</tr>
</tbody>
</table>

### OTHER OTOLOGICALS

#### Indifferent preparations

### CARBAMIDE PEROXIDE
Carbamide peroxide 6.5% ear drops, 12 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>20.57</td>
<td>6.30</td>
<td>Ear Clear for Ear Wax</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Removal [KY]</td>
</tr>
</tbody>
</table>

### DICHLOROBENZENE WITH CHLORBUTOL AND ARACHIS OIL
Dichlorobenzene with chlorbutol and arachis oil ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.75</td>
<td>6.30</td>
<td>Cerumol [UN]</td>
</tr>
</tbody>
</table>

### DOCUSATE
Docusate sodium 0.5% ear drops, 10 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>18.09</td>
<td>6.30</td>
<td>Waxsol [HM]</td>
</tr>
</tbody>
</table>

### VARIOUS

#### ALL OTHER THERAPEUTIC PRODUCTS

Drugs for treatment of hyperkalemia and hyperphosphatemia

### SODIUM POLYSTYRENE SULFONATE
Sodium polystyrene sulfonate 999.3 mg/g powder, 454 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>69.91</td>
<td>6.30</td>
<td>Resonium-A [SW]</td>
</tr>
</tbody>
</table>

### GENERAL NUTRIENTS

#### Other combinations of nutrients

### PROTEIN FORMULA WITH ARGinine, VITAMIN C AND E
**Restricted benefit**
Stage 2 and above pressure injury

**Clinical criteria:**
- The treatment must be for special medical purposes to support healing of pressure injuries.

Protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10850C</td>
<td>4</td>
<td>5</td>
<td>*158.63</td>
<td>6.30</td>
<td>Arginaid [NT]</td>
</tr>
</tbody>
</table>
VARIOUS

Clinical criteria:
- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C, E and zinc oral liquid, 27 x 237 mL cartons**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>10841N</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*263.19</td>
<td>Arginaid Extra [NT]</td>
</tr>
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</table>

**ALL OTHER NON-THERAPEUTIC PRODUCTS**

**LUBRICATING AGENT**

**lubricating agent jelly, 100 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4306P</td>
<td>1</td>
<td>..</td>
<td>14.32</td>
<td>6.30</td>
<td>Lubri-Gel [PP]</td>
</tr>
</tbody>
</table>

**Other non-therapeutic auxiliary products**

**BANDAGE ABSORBENT WOOL**

**bandage absorbent wool 10 cm x 3 m bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4653X</td>
<td>1</td>
<td>..</td>
<td>23.18</td>
<td>6.30</td>
<td>Surepress 650948 [CC]</td>
</tr>
</tbody>
</table>

**BANDAGE CALICO**

**bandage calico large triangular bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4717G</td>
<td>‡1</td>
<td>..</td>
<td>17.10</td>
<td>6.30</td>
<td>Handy 36361414 [BV]</td>
</tr>
</tbody>
</table>

**BANDAGE COMPRESSION**

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4654Y</td>
<td>5</td>
<td>..</td>
<td>*76.90</td>
<td>6.30</td>
<td>Comprilan 01027-00 [BV]</td>
</tr>
</tbody>
</table>

**b|andage compression 10 cm x 3 m high stretch bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4748X</td>
<td>5</td>
<td>..</td>
<td>*71.55</td>
<td>6.30</td>
<td>Surepress 650947 [CC]</td>
</tr>
</tbody>
</table>

**BANDAGE COMPRESSION**

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**bandage compression four layer bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4598B</td>
<td>5</td>
<td>..</td>
<td>*164.15</td>
<td>6.30</td>
<td>Profore Lite 66050415 [SN]</td>
</tr>
</tbody>
</table>

**bandage compression four layer bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4658E</td>
<td>5</td>
<td>..</td>
<td>*244.65</td>
<td>6.30</td>
<td>Profore 66050016 [SN]</td>
</tr>
</tbody>
</table>

**BANDAGE COMPRESSION**

**Note** Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

**bandage compression 10 cm x 3.5 m high stretch bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4657D</td>
<td>5</td>
<td>..</td>
<td>*76.70</td>
<td>6.30</td>
<td>Setopress 3505 [MH]</td>
</tr>
</tbody>
</table>
**BANDAGE COMPRESSION**

- **Note**: Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.
- **Note**: Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

**Restricted benefit**
- Venous ulcer
  - Treatment Phase: Initial treatment

**Restricted benefit**
- Venous ulcer
  - Treatment Phase: Continuing treatment

**Bandage Compression two layer bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4050E</td>
<td>1</td>
<td>..</td>
<td>42.85</td>
<td>6.30</td>
<td></td>
<td>Coban 2 [MM]</td>
</tr>
</tbody>
</table>

**BANDAGE RETENTION COHESIVE HEAVY**

**Bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4814J</td>
<td>2</td>
<td>..</td>
<td>*30.01</td>
<td>6.30</td>
<td></td>
<td>Peg 7425 [MM]</td>
</tr>
</tbody>
</table>

**Bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4812G</td>
<td>2</td>
<td>..</td>
<td>*20.55</td>
<td>6.30</td>
<td></td>
<td>Peg 7422 [MM]</td>
</tr>
</tbody>
</table>

**Bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4813H</td>
<td>2</td>
<td>..</td>
<td>*23.83</td>
<td>6.30</td>
<td></td>
<td>Peg 7423 [MM]</td>
</tr>
</tbody>
</table>

**Bandage retention cohesive heavy 10 cm x 2 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4660G</td>
<td>2</td>
<td>..</td>
<td>*22.35</td>
<td>6.30</td>
<td></td>
<td>Coban 1584 [MM]</td>
</tr>
</tbody>
</table>

**Bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4811F</td>
<td>2</td>
<td>..</td>
<td>*17.69</td>
<td>6.30</td>
<td></td>
<td>Peg 7420 [MM]</td>
</tr>
</tbody>
</table>

**BANDAGE RETENTION COHESIVE LIGHT**

**Bandage retention cohesive light 6 cm x 2 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4719J</td>
<td>2</td>
<td>..</td>
<td>*19.61</td>
<td>6.30</td>
<td></td>
<td>Handygauze Cohesive 8633 [BV]</td>
</tr>
</tbody>
</table>

**Bandage retention cohesive light 10 cm x 2 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4662J</td>
<td>2</td>
<td>..</td>
<td>*33.47</td>
<td>6.30</td>
<td></td>
<td>Handygauze Cohesive 8635 [BV]</td>
</tr>
</tbody>
</table>

**Bandage retention cohesive light 2.5 cm x 2 m bandage, 2**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4718H</td>
<td>..</td>
<td>..</td>
<td>17.23</td>
<td>6.30</td>
<td></td>
<td>Handygauze Cohesive 8631 [BV]</td>
</tr>
</tbody>
</table>

**BANDAGE RETENTION COTTON CREPE**

**Bandage retention cotton crepe 10 cm x 2.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4729X</td>
<td>2</td>
<td>..</td>
<td>*27.57</td>
<td>6.30</td>
<td></td>
<td>Telfa 8254F [KE]</td>
</tr>
</tbody>
</table>

**Bandage retention cotton crepe 5 cm x 2.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4727T</td>
<td>2</td>
<td>..</td>
<td>*20.65</td>
<td>6.30</td>
<td></td>
<td>Telfa 8252F [KE]</td>
</tr>
</tbody>
</table>

**Bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4728W</td>
<td>2</td>
<td>..</td>
<td>*24.83</td>
<td>6.30</td>
<td></td>
<td>Telfa 8253F [KE]</td>
</tr>
</tbody>
</table>
### BANDAGE TUBULAR

**bandage tubular size C (15 cm to 25 cm) straight bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4663K</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**bandage tubular size D (25 cm to 43 cm) straight bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4664L</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**bandage tubular size E (35 cm to 45 cm) straight bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4665M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### BANDAGE TUBULAR FINGER

**BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4798M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### BANDAGE TUBULAR LIGHT WEIGHT

**bandage tubular light weight 10 m small limb size bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4671W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**bandage tubular light weight 10 m large limb size bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4673Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**bandage tubular light weight 10 m medium limb size bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4672X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### BANDAGE TUBULAR LONG STOCKING

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
<th>Bandage Tubular Long Stocking</th>
<th>Small Size Bandage, 1</th>
<th>Medium Size Bandage, 1</th>
<th>Large Size Bandage, 1</th>
<th>XX/Large Size Bandage, 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>4674B</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
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<tr>
<td>4799N</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
</tr>
<tr>
<td>4675C</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
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<tr>
<td>4797L</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
</tr>
</tbody>
</table>

### BANDAGE TUBULAR SHORT STOCKING

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
<th>Bandage Tubular Short Stocking</th>
<th>Large/D size Bandage, 1</th>
<th>Medium/C size Bandage, 1</th>
<th>Small/B/C size Bandage, 1</th>
<th>Medium/B size Bandage, 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>4816L</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
</tr>
<tr>
<td>4815K</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
</tr>
<tr>
<td>4817L</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
</tr>
</tbody>
</table>

### BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

<table>
<thead>
<tr>
<th>Bandage Zinc Paste</th>
<th>10 cm x 9.1 m Bandage</th>
<th>7.5 cm x 6 m Bandage</th>
</tr>
</thead>
<tbody>
<tr>
<td>4670T</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
</tr>
<tr>
<td>4669R</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
</tr>
</tbody>
</table>

### Repatriation Pharmaceutical Benefits Scheme

[1607]
### BETaine + POLYaminopropyl Biguanide

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>86.29</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Viscopaste 4948 [SN]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### CADEXomer-IODINE

**Note** Suitable for yellow sloughy infected and malodorous wounds.

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### Dressing with CADEXomer IODINE Sheets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRESSING with CADEXomer IODINE Sheets 5 g (6 cm x 4 cm), 5, 1</td>
<td>4935R</td>
<td>2</td>
<td>..</td>
<td>111.81</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Iodosorb 66051330 [SN]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cadexomer-iodine 3 g sterile dusting powder, 7 sachets</td>
<td>4931M</td>
<td>2</td>
<td>..</td>
<td>74.91</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Iodosorb Powder 66051070 [SN]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRESSING with CADEXomer IODINE Sheets 17 g (10 cm x 8 cm), 2, 1</td>
<td>4937W</td>
<td>2</td>
<td>..</td>
<td>168.09</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Iodosorb 66051360 [SN]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cadexomer-iodine 50% ointment, 2 x 20 g</td>
<td>4933P</td>
<td>2</td>
<td>..</td>
<td>117.00</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Iodosorb Ointment 66051230 [SN]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet</td>
<td>4936T</td>
<td>2</td>
<td>..</td>
<td>159.73</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Iodosorb Ointment 66051240 [SN]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cadexomer-iodine 50% ointment, 4 x 10 g</td>
<td>4932N</td>
<td>2</td>
<td>..</td>
<td>118.06</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Iodosorb Ointment 66051240 [SN]</em></td>
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</table>

### Dressing Activated Charcoal Malodorous Wound

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10</td>
<td>4742N</td>
<td>2</td>
<td>..</td>
<td>77.05</td>
<td>6.30</td>
</tr>
<tr>
<td><em>CarboFLEX 403202 [CC]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5</td>
<td>4743P</td>
<td>2</td>
<td>..</td>
<td>86.95</td>
<td>6.30</td>
</tr>
<tr>
<td><em>CarboFLEX 403204 [CC]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1</td>
<td>4681J</td>
<td>2</td>
<td>..</td>
<td>*96.95</td>
<td>6.30</td>
</tr>
<tr>
<td><em>Actisorb Plus MAP105 [KI]</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Dressing Alginate Cavity Wound

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.
DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>*110.03</td>
<td>6.30</td>
<td>Kaltostat 168117 [CC]</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>*104.45</td>
<td>6.30</td>
<td>Sorbsan 1411 [UM]</td>
<td></td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE CAVITY WOUND**

*Note* This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

*Note* Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>*130.45</td>
<td>6.30</td>
<td>Comfeel SeaSorb Filler 3740 [CT]</td>
<td></td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note* This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<tr>
<td>†1</td>
<td>1</td>
<td>88.05</td>
<td>6.30</td>
<td>Kaltostat 168212 [CC]</td>
<td></td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note* This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

*Note* Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

Dressing alginate superficial wound 15 cm x 20 cm dressing, 10

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<tr>
<td>†1</td>
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<td>273.44</td>
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Dressing alginate superficial wound 5 cm x 5 cm dressing, 10

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<td>†1</td>
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<td>6.30</td>
<td>Kaltostat 168210 [CC]</td>
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<td>60.59</td>
<td>6.30</td>
<td>Algisite M 66000519 [SN]</td>
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Dressing alginate superficial wound 10 cm x 10 cm dressing, 10

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<tr>
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<td>113.67</td>
<td>6.30</td>
<td>Algisite M 66000520 [SN]</td>
<td></td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note* This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

*Note* Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Dressing alginate superficial wound 10 cm x 10 cm dressing, 1

<table>
<thead>
<tr>
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<tr>
<td>10</td>
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<td>*81.95</td>
<td>6.30</td>
<td>Sorbsan 1410 [UM]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>*87.15</td>
<td>6.30</td>
<td>Comfeel SeaSorb Dressing 3710 [CT]</td>
<td></td>
</tr>
</tbody>
</table>
### DRESSING ALGINATE WITH MANUKA HONEY

*Note Suitable for yellow sloughy infected and malodorous wounds.*

**dressing alginate with manuka honey 2.5 cm x 20 cm ribbon, 5**

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<tr>
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<td>4</td>
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<td>Algivon Plus Ribbon &amp; Probe CR4231 [DJ]</td>
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**dressing alginate with manuka honey 10 cm x 10 cm dressing, 5**

<table>
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### DRESSING FILM

**dressing film 15 cm x 20 cm dressing, 1**

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<tr>
<td>6</td>
<td>..</td>
<td>*32.17</td>
<td>6.30</td>
<td></td>
<td>Tegaderm Transparent 1628 [MM]</td>
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**dressing film 10 cm x 12 cm dressing, 4**

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<tr>
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<td>Nexcare Tegaderm Transparent H1626 [MM]</td>
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**dressing film 6 cm x 7 cm dressing, 8**

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<td></td>
<td>Nexcare Tegaderm Transparent H1624 [MM]</td>
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### DRESSING FILM ISLAND

**dressing film island 9 cm x 10 cm dressing, 1**

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<tr>
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<td></td>
<td>Tegaderm Transparent Island 3586 [MM]</td>
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**dressing film island 5 cm x 7 cm dressing, 1**

<table>
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<td></td>
<td>Tegaderm Transparent Island 3582 [MM]</td>
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</table>

### DRESSING FILM ISLAND

*Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.*

**dressing film island 5 cm x 7.2 cm dressing, 5**

<table>
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<tr>
<td>2</td>
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<td></td>
<td>Cutfilm Plus 36361370 [SN]</td>
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</tbody>
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**NOTE**

- Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.
DRESSING FOAM HEAVY EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

DRESSING FOAM MODERATE EXUDATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

DRESSING FOAM WITH SILICONE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

DRESSING FOAM WITH SILICONE AND SILVER

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

Authority required
Wounds

Clinical criteria:
- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**DRESSING FOAM WITH SILICONE LIGHT EXUDATE**

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

**DRESSING FOAM WITH SILICONE MODERATE EXUDATE**

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.
**DRESSING FOAM WITH SILVER**

*Note* Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### Authority required

**Wounds**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### DRESSING FOAM WITH SILVER

#### dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

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<td>42.85</td>
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Mepilex 294100 [MH]

#### dressing foam with silver 10 cm x 10 cm dressing, 10

<table>
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<td>‡1</td>
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Allevyn Ag Adhesive 66800075 [SN]

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Allevyn Ag Non-Adhesive 66800086 [SN]

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Allevyn Ag Gentle Border 66800461 [SN]

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Allevyn Ag Gentle Border 66800462 [SN]

### DRESSING GAUZE ABSORBENT

#### dressing gauze absorbent 5 cm x 5 cm pad, 100

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Handy 71117-05 [BV]

#### dressing gauze absorbent 10 cm x 10 cm pad, 100

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Handy 71117-06 [BV]

### DRESSING GAUZE EYE

#### dressing gauze eye pad, 12 pads

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<td>16.66</td>
<td>6.30</td>
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</tr>
</tbody>
</table>

Curity 4112 [KE]

### DRESSING GAUZE PARAFFIN

*Note* Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler...
cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### DRESSING GAUZE PARAFFIN 10 cm x 10 cm dressing, 10

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<td>Jelonet 7404 [SN]</td>
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</table>

### DRESSING HYDROACTIVE DEBRIDEMENT

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

### DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1

<table>
<thead>
<tr>
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<td>TenderWet 24 Active 609213 [HR]</td>
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### DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1

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<td>84.28</td>
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### DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1

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</table>

### DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>128.74</td>
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<td>Tielle MTL103 [KI]</td>
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</table>

### DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<td>Tielle MTL101E [KI]</td>
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### DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

<table>
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<td>CombiDERM 651031 [CC]</td>
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</tbody>
</table>
### DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<td>6.30</td>
<td>Allevyn Thin 66047578 [SN]</td>
</tr>
<tr>
<td>4905E</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>66.34</td>
<td>6.30</td>
<td>Allevyn Thin 66047576 [SN]</td>
</tr>
</tbody>
</table>

### DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4885D</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>56.44</td>
<td>6.30</td>
<td>Cutinova Hydro 66047441 [SN]</td>
</tr>
<tr>
<td>4886E</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*92.49</td>
<td>6.30</td>
<td>Cutinova Hydro 66047443 [SN]</td>
</tr>
</tbody>
</table>

### DRESSING HYDROCOLLOID CAVITY WOUND

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4896Q</td>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*137.15</td>
<td>6.30</td>
<td>DuoDERM Paste H7930 [CC]</td>
</tr>
</tbody>
</table>

### DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4907G</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>70.45</td>
<td>6.30</td>
<td>DuoDERM Extra Thin H7955 [CC]</td>
</tr>
</tbody>
</table>
**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

Note: This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

Note: Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Light Exudate 10 cm x 10 cm dressing, 10</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>68.69</td>
<td>6.30</td>
<td></td>
<td>Comfeel Plus Transparent 3533 [CT]</td>
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<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Light Exudate 5 cm x 7 cm dressing, 10</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
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<td>41.89</td>
<td>6.30</td>
<td></td>
<td>Comfeel Plus Transparent 3530 [CT]</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Light Exudate 9 cm x 14 cm dressing, 10</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>82.09</td>
<td>6.30</td>
<td></td>
<td>Comfeel Plus Transparent 3536 [CT]</td>
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</tbody>
</table>

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

Note: This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note: Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Moderate Exudate 20 cm x 20 cm dressing, 5</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*209.61</td>
<td>6.30</td>
<td></td>
<td>DuoDERM CGF H7662 [CC]</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Moderate Exudate 10 cm x 10 cm dressing, 5</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*79.25</td>
<td>6.30</td>
<td></td>
<td>DuoDERM CGF H7660 [CC]</td>
</tr>
</tbody>
</table>

**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

Note: This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note: Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Moderate Exudate 10 cm x 10 cm dressing, 10</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>93.46</td>
<td>6.30</td>
<td></td>
<td>Replicare Ultra 66000434 [SN]</td>
</tr>
</tbody>
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**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

Note: This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note: Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
<thead>
<tr>
<th>Dressing Hydrocolloid Superficial Wound Moderate Exudate 10 cm x 10 cm dressing, 10</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>48.32</td>
<td>6.30</td>
<td></td>
<td>Hydrocoll 900744 [HR]</td>
</tr>
</tbody>
</table>
### DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

**Note** This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
<thead>
<tr>
<th>MaxQty Packs</th>
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<tr>
<td>4946H</td>
<td>1</td>
<td></td>
<td>86.99</td>
<td>6.30</td>
<td>Hydrocoll 900936 [HR]</td>
</tr>
</tbody>
</table>

### DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE 10cm (round) dressing, 1

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4679G</td>
<td>5</td>
<td></td>
<td>*59.45</td>
<td>6.30</td>
<td>Comfeel Pressure Relieving 3353 [CT]</td>
</tr>
</tbody>
</table>

### DRESSING HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 1

<table>
<thead>
<tr>
<th>MaxQty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4923D</td>
<td>1</td>
<td></td>
<td>79.80</td>
<td>6.30</td>
<td>Comfeel Plus Ulcer Dressing 3110 [CT]</td>
</tr>
</tbody>
</table>

### DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>MaxQty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10832D</td>
<td>1</td>
<td></td>
<td>116.73</td>
<td>6.30</td>
<td>Aqacel Foam Adhesive [CC]</td>
</tr>
<tr>
<td>10837J</td>
<td>1</td>
<td></td>
<td>120.20</td>
<td>6.30</td>
<td>Aqacel Foam Non-Adhesive [CC]</td>
</tr>
<tr>
<td>2797F</td>
<td>1</td>
<td></td>
<td>97.05</td>
<td>6.30</td>
<td>Aqacel Extra 420672 [CC]</td>
</tr>
<tr>
<td>4698G</td>
<td>1</td>
<td></td>
<td>81.35</td>
<td>6.30</td>
<td>Aqacel 403770 [CC]</td>
</tr>
<tr>
<td>2803M</td>
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<td></td>
<td>*195.51</td>
<td>6.30</td>
<td>Aqacel Extra 420673 [CC]</td>
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</table>

### DRESSING HYDROFIBRE GELLING FIBRE

<table>
<thead>
<tr>
<th>MaxQty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2462N</td>
<td>1</td>
<td></td>
<td>87.24</td>
<td>6.30</td>
<td>Durafiber 66800563 [SN]</td>
</tr>
<tr>
<td>2486W</td>
<td>1</td>
<td></td>
<td>103.62</td>
<td>6.30</td>
<td>Durafiber 66800560 [SN]</td>
</tr>
<tr>
<td>2445Q</td>
<td>2</td>
<td></td>
<td>*211.59</td>
<td>6.30</td>
<td>Durafiber 66800561 [SN]</td>
</tr>
</tbody>
</table>
**DRESSING HYDROFIBRE WITH SILVER**

**Authority required**

**Wounds Clinical criteria:**
- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

### dressing hydrofibre with silver 2 cm x 45 cm rope, 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td>..</td>
<td>211.81</td>
<td>6.30</td>
<td>Aquacel Ag 403771 [CC]</td>
</tr>
</tbody>
</table>

### dressing hydrofibre with silver 10 cm x 10 cm dressing, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td>..</td>
<td>250.75</td>
<td>6.30</td>
<td>Aquacel Ag 403708 [CC]</td>
</tr>
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</table>

### dressing hydrofibre with silver 15 cm x 15 cm dressing, 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td>..</td>
<td>268.39</td>
<td>6.30</td>
<td>Aquacel Ag 403710 [CC]</td>
</tr>
</tbody>
</table>

**DRESSING HYDROGEL**

### dressing hydrogel 10 cm x 10 cm dressing, 20

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2471C</td>
<td>1</td>
<td>..</td>
<td>108.93</td>
<td>6.30</td>
<td>Sorbact Absorption Dressing S98222 [QL]</td>
</tr>
</tbody>
</table>

**Note**  This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

### dressing hydrogel amorphous gel, 3 x 30 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4913N</td>
<td>3</td>
<td>1</td>
<td>*93.52</td>
<td>6.30</td>
<td>DuoDERM Gel H7987 [CC]</td>
</tr>
</tbody>
</table>

### dressing hydrogel amorphous gel, 50 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4914P</td>
<td>3</td>
<td>3</td>
<td>*34.30</td>
<td>6.30</td>
<td>Solugel 10336 [JJ]</td>
</tr>
</tbody>
</table>

**DRESSING HYDROGEL AMORPHOUS**

**Note**  This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note**  Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### dressing hydrogel amorphous gel, 10 x 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>4912M</td>
<td>†1</td>
<td>1</td>
<td>63.87</td>
<td>6.30</td>
<td>DuoDERM Gel H7990 [CC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>70.79</td>
<td>6.30</td>
<td>Comfeel Purlon Gel 3900 [CT]</td>
</tr>
</tbody>
</table>

**DRESSING HYDROGEL AMORPHOUS**

**Note**  This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note**  Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing hydrogel amorphous gel, 50 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4599C</td>
<td>3</td>
<td>3</td>
<td>*34.75</td>
<td>6.30</td>
<td>SoloSite Gel 36361338 [SN]</td>
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</table>
dressing hydrogel amorphous gel, 25 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nu-Gel 2497 [KI]</td>
<td>2</td>
<td>..</td>
<td>*80.89</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING HYDROGEL FOAM

Dressing hydrogel foam 10 cm x 10 cm dressing, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbact Foam Dressing S98310 [QL]</td>
<td>1</td>
<td>..</td>
<td>77.48</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING HYDROGEL RIBBON

Dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbact Ribbon Gauze S98120 [QL]</td>
<td>1</td>
<td>..</td>
<td>108.93</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

Dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbact Ribbon Gauze S98115 [QL]</td>
<td>2</td>
<td>..</td>
<td>112.43</td>
<td>6.30</td>
<td></td>
</tr>
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</table>

DRESSING HYDROGEL SHEET

Note: This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

Dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Nu-Gel 2497 [KI]</td>
<td>2</td>
<td>..</td>
<td>*80.89</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING HYDROGEL SHEET

Note: This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

Dressing hydrogel sheet 10 cm x 10 cm dressing, 5

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrosorb 900854 [HR]</td>
<td>2</td>
<td>..</td>
<td>*53.45</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING NON ADHERENT

Note: Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

Dressing self adhesive non-adherent dry absorbent dressings, non-woven, with silicone 7.5 cm x 10 cm, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mepitel 290710 [MH]</td>
<td>1‡</td>
<td>..</td>
<td>103.09</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mepitel 290510 [MH]</td>
<td>1‡</td>
<td>..</td>
<td>63.09</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING NON ADHERENT

Note: Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

Dressing non adherent 7.5 cm x 10 cm dressing, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrauman 499513 [HR]</td>
<td>1‡</td>
<td>..</td>
<td>18.76</td>
<td>6.30</td>
<td></td>
</tr>
</tbody>
</table>
**DRESSING NON ADHERENT**

*Note* Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<p>| dressing non adherent 10 cm x 10 cm dressing, 5 |</p>
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4862X</td>
<td>2</td>
<td>..</td>
<td>*28.93</td>
<td>6.30</td>
<td>Cutilin Non-Stick Wound Pad 36361376 [SN]</td>
</tr>
</tbody>
</table>

<p>| dressing non adherent 10 cm x 10 cm dressing, 10 |</p>
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4861W</td>
<td>..</td>
<td>..</td>
<td>39.21</td>
<td>6.30</td>
<td>Melolin 66974933 [SN]</td>
</tr>
</tbody>
</table>

<p>| dressing non adherent 5 cm x 5 cm dressing, 5 |</p>
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4819P</td>
<td>2</td>
<td>..</td>
<td>*19.89</td>
<td>6.30</td>
<td>Cutilin Non-Stick Wound Pad 36361374 [SN]</td>
</tr>
</tbody>
</table>

<p>| dressing non adherent 5 cm x 5 cm dressing, 5 |</p>
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4860T</td>
<td>2</td>
<td>..</td>
<td>*21.13</td>
<td>6.30</td>
<td>Melolin 36361357 [SN]</td>
</tr>
</tbody>
</table>

**DRESSING TULLE NON GAUZE PARRAFIN**

dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4909J</td>
<td>10</td>
<td>1</td>
<td>*19.15</td>
<td>6.30</td>
<td>Adaptic 2012 [KI]</td>
</tr>
</tbody>
</table>

**DRESSING WITH SILVER**

*Note* Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

**Authority required**

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing with silver 12.5 cm x 12.5 cm hydroactive dressing, 5**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4647N</td>
<td>1</td>
<td></td>
<td>179.15</td>
<td>6.30</td>
<td>Biatain Ag 9632 [CT]</td>
</tr>
</tbody>
</table>

**dressing with silver 10 cm x 10 cm hydroactive dressing, 5**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4646M</td>
<td>1</td>
<td></td>
<td>165.14</td>
<td>6.30</td>
<td>Biatain Ag 9622 [CT]</td>
</tr>
</tbody>
</table>

**DRESSING WITH SILVER**

*Note* Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**Authority required**

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**dressing with silver 10 cm x 10 cm tulle dressing, 3**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4648P</td>
<td>1</td>
<td></td>
<td>43.95</td>
<td>6.30</td>
<td>Atrauman Ag 499572 [HR]</td>
</tr>
</tbody>
</table>
**GAUGE AND COTTON TISSUE COMBINE ROLL**

gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4761N</td>
<td>†1</td>
<td>20.47</td>
<td>6.30</td>
<td>JJ 12010 [JJ]</td>
<td></td>
</tr>
</tbody>
</table>


**POVIDONE-IODINE**
povidone-iodine 9.5 cm x 9.5 cm dressing, 25

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10847X</td>
<td>†1</td>
<td>77.64</td>
<td>6.30</td>
<td>Mauvex [KI]</td>
<td></td>
</tr>
</tbody>
</table>


**SODIUM CHLORIDE + HOPIHOCLOROUS ACID + SODIUM HYPOCHLORITE**
sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11134B</td>
<td>†1</td>
<td>30.44</td>
<td>6.30</td>
<td>Microdacyn [TF]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE NON WOVEN RETENTION POLYACRYLATE**
tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4915Q</td>
<td>†1</td>
<td>16.70</td>
<td>6.30</td>
<td>Medipore 2961 [MM]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE NON WOVEN RETENTION POLYACRYLATE**

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tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4917T</td>
<td>†1</td>
<td>17.62</td>
<td>6.30</td>
<td>Leukoplast 01071-00 [BV]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE PLASTER ADHESIVE ELASTIC**
tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4781P</td>
<td>†1</td>
<td>23.56</td>
<td>6.30</td>
<td>Leukoplast 01072-00 [BV]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE PLASTER ADHESIVE ELASTIC**
tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4782Q</td>
<td>†1</td>
<td>27.24</td>
<td>6.30</td>
<td>Leukoplast 01073-00 [BV]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE PLASTER ADHESIVE ELASTIC**
tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4780N</td>
<td>†1</td>
<td>17.62</td>
<td>6.30</td>
<td>Leukoplast 01071-00 [BV]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE PLASTER ADHESIVE HYPOALLERGENIC**
tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4783R</td>
<td>†1</td>
<td>15.03</td>
<td>6.30</td>
<td>Leukopor 2471 [BV]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE PLASTER ADHESIVE HYPOALLERGENIC**
tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4785W</td>
<td>†1</td>
<td>15.32</td>
<td>6.30</td>
<td>Leukosilk 1021 [BV]</td>
<td></td>
</tr>
</tbody>
</table>


**TAPE PLASTER ADHESIVE HYPOALLERGENIC**
tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

<table>
<thead>
<tr>
<th>No.</th>
<th>Quantity</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4788B</td>
<td>†1</td>
<td>20.47</td>
<td>6.30</td>
<td>Leukoflex 1124 [BV]</td>
<td></td>
</tr>
</tbody>
</table>
### Tape Plaster Adhesive Hypoallergenic 5 cm x 5 m Stretch Tape, 1 Roll

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4787C</td>
<td>Tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>21.79</td>
<td>6.30</td>
<td></td>
<td>Leukosilk 1024 [BV]</td>
</tr>
<tr>
<td>4790D</td>
<td>Tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>20.96</td>
<td>6.30</td>
<td></td>
<td>Leukopor 2474 [BV]</td>
</tr>
</tbody>
</table>

### Tape Plaster Adhesive Hypoallergenic 1.9 cm x 5.4 m Dispenser Tape, 1 Roll

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4848E</td>
<td>Tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>15.12</td>
<td>6.30</td>
<td></td>
<td>Nexcare Durable Cloth First Aid Tape 799 [MM]</td>
</tr>
</tbody>
</table>

### Tape Plaster Adhesive Hypoallergenic 2.5 cm x 5 m Tape, 1 Roll

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4787Y</td>
<td>Tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>17.97</td>
<td>6.30</td>
<td></td>
<td>Leukosilk 1022 [BV]</td>
</tr>
<tr>
<td>4794H</td>
<td>Tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>17.44</td>
<td>6.30</td>
<td></td>
<td>Leukopor 2472 [BV]</td>
</tr>
</tbody>
</table>

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### Tape Plaster Adhesive with Silicone

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4239D</td>
<td>Tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>24.09</td>
<td>6.30</td>
<td></td>
<td>Mepitac 298300 [MH]</td>
</tr>
<tr>
<td>4240E</td>
<td>Tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>24.09</td>
<td>6.30</td>
<td></td>
<td>Mepitac 298400 [MH]</td>
</tr>
</tbody>
</table>
Extemporaneously Prepared Benefits
<table>
<thead>
<tr>
<th>Drug</th>
<th>Standard</th>
<th>Recovery Prices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0.1 g/mL</td>
</tr>
<tr>
<td>Acacia Mucilage (by weight)</td>
<td>APF 15</td>
<td>0.02</td>
</tr>
<tr>
<td>Acacia, powdered</td>
<td>BP</td>
<td>0.03</td>
</tr>
<tr>
<td>Acetic Acid (33 per cent)</td>
<td>BP</td>
<td>0.01</td>
</tr>
<tr>
<td>Acetic Acid (6 per cent)</td>
<td>BP</td>
<td>0.01</td>
</tr>
<tr>
<td>Acetic Acid Glacial BP</td>
<td>BP</td>
<td>0.02</td>
</tr>
<tr>
<td>Acetone (use as additive only)</td>
<td>BP</td>
<td>0.03</td>
</tr>
<tr>
<td>Acetic Acid Glacial BP</td>
<td>BP</td>
<td>0.03</td>
</tr>
<tr>
<td>Acetic Acid Glacial BP</td>
<td>BP</td>
<td>0.03</td>
</tr>
<tr>
<td>Acetone (use as additive only)</td>
<td>BP</td>
<td>0.03</td>
</tr>
<tr>
<td>Anise Oil BP</td>
<td>BP</td>
<td>0.02</td>
</tr>
<tr>
<td>Anise Water Concentrated 1 in 40</td>
<td>BP</td>
<td>0.01</td>
</tr>
<tr>
<td>Aqueous Cream (for use only as a base combined with active</td>
<td>APF</td>
<td>0.01</td>
</tr>
<tr>
<td>ingredients)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ascorbic Acid (for use only as an ingredient of ferrous</td>
<td>BP</td>
<td>0.37</td>
</tr>
<tr>
<td>sulfate mixtures)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belladonna Tincture</td>
<td>BP</td>
<td>0.10</td>
</tr>
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"Extemp"
## Container Prices

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## Standard Formula Preparations

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